

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
30 January 2003 (30.01.2003)

PCT

(10) International Publication Number
WO 03/007839 A2

(51) International Patent Classification⁷: **A61F**

(21) International Application Number: PCT/US02/23189

(22) International Filing Date: 15 July 2002 (15.07.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/305,786 16 July 2001 (16.07.2001) US
60/389,028 14 June 2002 (14.06.2002) US

(71) Applicant (*for all designated States except US*): **DEPUY PRODUCTS, INC.** [US/US]; 700 Orthopaedic Drive, Warsaw, IN 46581 (US).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **PELO, Mark, Joseph** [US/US]; 14180 E 400 S, Macy, IN 46951 (US). **PLOUHAR, Pamela, Lynn** [US/US]; 17411 Battles Road, South Bend, IN 46614 (US). **SCHWARTZ, Herbert, Eugene** [US/US]; 11702 Pennat Run, Fort Wayne, IN 46845 (US). **MALAVIYA, Prasanna** [IN/US]; 3610 Winterfield Run, Fort Wayne, IN 46804 (US). **WHALEN, Terrence, David** [CA/US]; 4107 East Postawatami Lane, Leesburg, IN 46538 (US).

(74) Agent: **COFFEY, William, R.**; Barnes & Thornburg, 11 South Meridian Street, Indianapolis, IN 46204 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

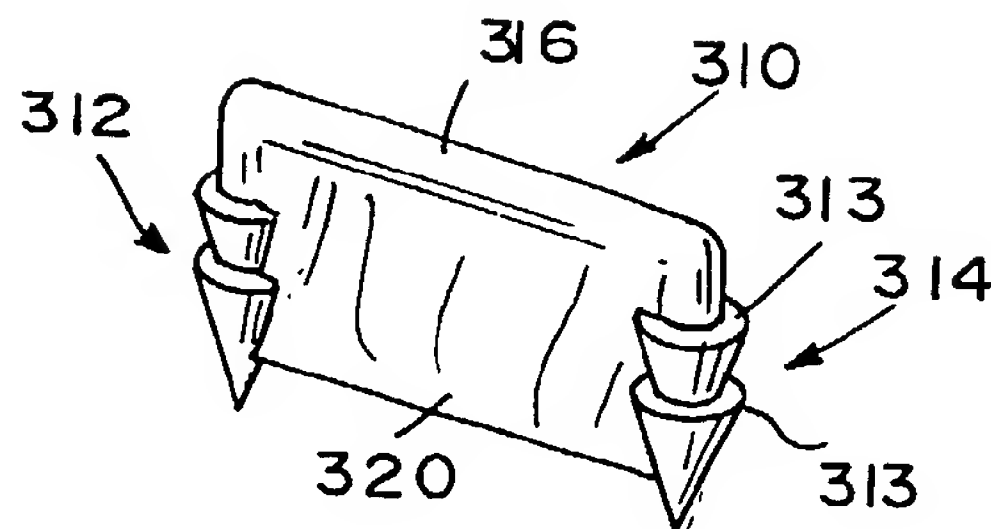
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DEVICES FORM NATURALLY OCCURRING BIOLOGICALLY DERIVED



(57) Abstract: Orthopaedic devices are disclosed. The devices (16) include a part that is made of extracellular matrix material that has been hardened. One method of hardening the extracellular matrix is to comminute naturally occurring extracellular matrix and dry the comminuted material. The hardened extracellular matrix material can be machined to form a variety of orthopaedic devices.

WO 03/007839 A2

DEVICES FROM NATURALLY OCCURRING BIOLOGICALLY DERIVED MATERIALS

CROSS REFERENCE TO RELATED APPLICATIONS

5 Cross reference is made to co-pending U.S. patent applications Serial No. XX/XXX,XXX entitled "Meniscus Regeneration Device and Method" (Attorney Docket No. 265280-71141, DEP-745); Serial No. XX/XXX,XXX entitled "Cartilage Repair Apparatus and Method" (Attorney Docket No. 265280-71143, DEP-749); Serial No. XX/XXX,XXX entitled "Unitary Surgical Device and Method" (Attorney Docket No. DEP-750); Serial No. XX/XXX,XXX entitled "Hybrid Biologic/Synthetic Porous Extracellular Matrix Scaffolds" (Attorney Docket No. 265280-71144, DEP-751); Serial No. XX/XXX,XXX entitled "Cartilage Repair and Regeneration Device and Method" (Attorney Docket No. 265280-71145, DEP-752); Serial No. XX/XXX,XXX entitled "Porous Extracellular Matrix Scaffold and Method" (Attorney Docket No. 265280-71146, DEP-747); Serial No. XX/XXX,XXX entitled "Cartilage Repair and Regeneration Scaffolds and Method" (Attorney Docket No. 265280-71180, DEP-763); and Serial No. XX/XXX,XXX entitled "Porous Delivery Scaffold and Method" (Attorney Docket No. 265280-71207, DEP-762), each of which is assigned to the same assignee as the present application, each of which is filed concurrently herewith, and each of which is hereby incorporated by reference. Cross reference is also made to U.S. Patent Application Serial No. 10/172,347 entitled "Hybrid Biologic-Synthetic Bioabsorbable Scaffolds" which was filed on June 14, 2002, which is assigned to the same assignee as the present application, and which is hereby incorporated by reference.

25

BACKGROUND AND SUMMARY OF THE INVENTION

The present invention relates to devices for attaching, repairing or regenerating orthopedic tissue, particularly to such devices made from naturally occurring extracellular matrix cured or treated to have structural rigidity and hardness.

30

It is known to use various collagen scaffolds to provide a scaffold for repair and regeneration of damaged tissue. U.S. Patent No. 6,042,610 to ReGen Biologics, hereby incorporated by reference, discloses the use of a device comprising

-2-

a bioabsorbable material made at least in part from purified natural fibers. The purified natural fibers are cross-linked to form the device of U.S. Patent No. 6,042,610. The device can be used to provide augmentation for a damaged meniscus. Related U.S. Patents Nos. 5,735,903, 5,479,033, 5,306,311, 5,007,934, and 4,880,429
5 also disclose a meniscal augmentation device for establishing a scaffold adapted for ingrowth of meniscal fibrochondrocyts.

It is also known to use naturally occurring extracellular matrices (ECMs) to provide a scaffold for tissue repair and regeneration. One such ECM is small intestine submucosa (SIS). SIS has been described as a natural acellular
10 biomaterial used to repair, support, and stabilize a wide variety of anatomical defects and traumatic injuries. See, for example, Cook® Online New Release provided by Cook Biotech Inc. at “www.cookgroup.com”. The SIS material is derived from porcine small intestinal submucosa that models the qualities of its host when implanted in human soft tissues. Further, it is taught that the SIS material provides a
15 natural scaffold-like matrix with a three-dimensional structure and biochemical composition that attracts host cells and supports tissue remodeling. SIS products, such as OASIS and SURGISIS, are commercially available from Cook Biotech Inc., Bloomington, IN.

Another SIS product, RESTORE Orthobiologic Implant, is available
20 from DePuy Orthopaedics, Inc. in Warsaw, Indiana. The DePuy product is described for use during rotator cuff surgery, and is provided as a resorbable framework that allows the rotator cuff tendon to regenerate. The RESTORE Implant is derived from porcine small intestine submucosa, a naturally occurring ECM (composed of mostly collagen type I (about 90% of dry weight) glycosaminoglycans and other biological
25 molecules), that has been cleaned, disinfected, and sterilized. During seven years of preclinical testing in animals, there were no incidences of infection transmission from the implant to the host, and the RESTORE Implant has not adversely affected the systemic activity of the immune system.

While small intestine submucosa is available, other sources of
30 submucosa are known to be effective for tissue remodeling. These sources include, but are not limited to, stomach, bladder, alimentary, respiratory, or genital submucosa, or liver basement membrane. See, e.g., U.S. Patents Nos. 6,379,710, 6,171,344, 6,099,567, and 5,554,389, hereby incorporated by reference. Further, while SIS is

-3-

most often porcine derived, it is known that these various submucosa materials may be derived from non-porcine sources, including bovine and ovine sources.

Additionally, the ECM material may also include partial layers of lamina muscularis mucosa, muscularis mucosa, lamina propria, stratum compactum and/or other tissue materials depending upon factors such as the source from which the ECM material was derived and the delamination procedure.

For the purposes of this invention, it is within the definition of a naturally occurring ECM to clean and/or comminute the ECM, or to cross-link the collagen within the ECM. It is also within the definition of naturally occurring extracellular matrix to fully or partially remove one or more components or subcomponents of the naturally occurring matrix. However, it is not within the definition of a naturally occurring ECM to extract, separate and purify the natural components or sub-components and reform a matrix material from purified natural components or sub-components. Also, while reference is made to SIS, it is understood that other naturally occurring ECMs (e.g., stomach, bladder, alimentary, respiratory or genital submucosa, and liver basement membrane), whatever the source (e.g., bovine, porcine, ovine) are within the scope of this invention. Thus, in this application, the terms "naturally occurring extracellular matrix" or "naturally occurring ECM" are intended to refer to extracellular matrix material that has been cleaned, disinfected, sterilized, and optionally cross-linked.

The following U.S. patents, hereby incorporated by reference, disclose the use of ECMs for the regeneration and repair of various tissues: 6,379,710; 6,187,039; 6,176,880; 6,126,686; 6,099,567; 6,096,347; 5,997,575; 5,993,844; 5,968,096; 5,955,110; 5,922,028; 5,885,619; 5,788,625; 5,762,966; 5,755,791; 5,753,267; 5,733,337; 5,711,969; 5,645,860; 5,641,518; 5,554,389; 5,516,533; 5,445,833; 5,372,821; 5,352,463; 5,281,422; and 5,275,826. U.S. Patent No. 5,352,463 discloses an SIS pillow filled with comminuted SIS for regeneration of a meniscus. While U.S. Patent No. 5,352,463 contemplates the general concept of meniscus regeneration with an SIS filled pouch, it does not address itself to providing such a pouch having the capability of withstanding the compression and shear stresses involved in an implant for regenerating a meniscus. Also, U.S. Patent No. 5,352,463 does not contemplate placing structural members formed from naturally occurring ECM, where in the ECM is right and hardened.

-4-

It is known to use materials such as catgut and SIS to make appliances. See WO 95/06439 to Bolesky. The Bolesky application discloses devices that are semi-rigid and are formed into desired shapes, but Bolesky does not disclose a process for fabricating naturally occurring extracellular matrix parts that are rigid and
5 hardened.

In the present invention, the density and porosity of the extracellular matrix material can be controlled with drying protocols, including air drying, air drying with heat, and air drying with pressure. Thus, the ECM material can be dried to have a hardness sufficient to machine the device, without the need to form the
10 device into the general shape by molding. By managing density and porosity of the ECM, various fixation devices can be made having superior material properties, wherein the devices promote healing while remaining biocompatible and biodegradable.

The present invention, in one of its embodiments, is an orthopedic
15 device for attaching soft tissue such as cartilage, ligaments, and tendons to bone. The device, which in one embodiment has a head end portion configured to engage soft tissue and a body portion configured to engage and attach to the bone, is preferably monolithic and formed as a unitary structure from naturally occurring extracellular matrix. The body portion of the device may illustratively terminate with a pointed
20 end distal from the head portion to facilitate the penetration into the bone. Between the pointed distal end and the head portion, the device may illustratively be formed with radially outwardly extending barbs. These barbs may incline toward the head portion to provide a barbed tack or tack-like device. In some embodiments, a body portion is provided with diametrically opposed flats extending therealong, the flats
25 being generally parallel.

It has been found that a mass of naturally occurring ECM may be cured to be very rigid and hardened so that it can be machined using conventional cutting tools and using laser machining. The devices of this invention may be formed by machining a mass of cured matrix to define the head portion and body portion.
30 The mass may be formed by compressing the ECM into a solid mass. For example, the ECM may be comminuted and formed into a solid mass with interlocking strands of ECM.

-5-

For example, a tightly balled or compacted mass of pieces of SIS, illustratively comminuted SIS, can be formed by air drying or by hot air drying to become extremely hard. Unexpectedly, this hardened SIS can be machined or formed to have very sharp pointed ends, sharp barbs, etc. With this process, tacks, barbed
5 tacks, and threaded elements may be machined from such cured mass of SIS. The tacks may be double-ended tacks or may include a central head portion and a sharpened body portion extending axially from each end of the head portion. Alternatively, a device may be made such that one body portion may be threaded while another body portion has barbs.

10 In one embodiment, such tacks or barbs may be attached to devices made of naturally occurring extracellular matrix laminated together to form a body portion. For example, such a body portion may be fabricated to be placed into the tear of a meniscus to extend along the tear. One or more tacks or barbs made in accordance with the present invention may be coupled to the body portion to secure
15 the device in the tear. Each of these tacks may be made from naturally occurring extracellular matrix cured to be hard and rigid.

A staple or a staple-like device may be fabricated in accordance with the present invention utilizing two or more spaced apart barbs, each having a sharpened distal end and a proximal end. A connecting member may be placed
20 between the proximal ends of the barbs. This connecting member may itself be made from a material such as SIS and optionally may be formed integrally with the barbs. Thus, in accordance with the present invention, an orthopedic staple device may be made from naturally occurring extracellular matrix hardened to have two or more sharpened barbs connected by strands of extracellular matrix such as SIS. In some
25 embodiments of the present invention, such a staple or staple-like device may be made by laminating several layers of naturally occurring extracellular matrix and curing the layers to form a rigid and hardened sheet-like body. The barbs and the connecting member or members are then cut from the body. It has been found that the barbs and connecting member may be cut by laser machining a pattern on the
30 sheet-like body. It has also been found that such barbs may be formed to have edges fused together by the laser machining process.

In another embodiment, a device for anchoring a bone plug in an opening formed in a bone is provided. The device comprises a mass of naturally

-6-

occurring extracellular matrix formed into a rigid and hardened member configured to be wedged in the opening between the bone plug and the bone. This rigid and hardened member may be formed with outwardly extending barbs to dig into the bone plug and the bone. The device may also have a connecting portion to extend into an opening in the bone plug. In some embodiments, the member is designed to extend axially along side the bone plug, and the member may have a plurality of radially outwardly and longitudinally extending fins to dig into the bone plug and the bone. The elongated member may be cannulated so that it may be guided into place on a guide member such as a K-wire. In some embodiments, the member may be formed in the shape of a screw to be threaded into the opening between the bone plug and the bone.

There is provided, therefore, a method for anchoring a bone plug into an opening formed in a bone for receiving a plug, the method comprising the steps of providing a member formed into a rigid and hardened mass of naturally occurring extracellular matrix and placing the member into the opening between the bone and the bone plug. In some embodiments, the bone opening will be formed with a cylindrical wall and a bottom (or upper end) to receive a cylindrical bone plug, and the placing step will comprise placing the member in the bone plug to engage the bone plug and the bone. The member may be a double-ended tack, one end of which extends into the bottom of the opening and the other end of which extends into the bone plug. The double ended tack may radially expand the plug to engage the wall of the opening.

In another embodiment, a device for attaching a soft tissue such as a tendon, ligament, or ligament replacement has been provided. The device, which is formed from a hardened mass of naturally occurring extracellular matrix, is provided with an elongated body to be received in the opening in the bone. The body has a channel therein for receiving a portion of the soft tissue. This body is configured to collapse inwardly to grip and hold the soft tissue in the channel when the body is inserted into the opening. In some embodiments, the body may be threaded to accomplish inserting the device into the opening. It will be appreciated that such a device may be used for attaching an ACL replacement ligament in a tunnel formed in a femur, wherein the tunnel has an axis and a generally cylindrical wall. Such tunnel formation is known in the ACL replacement art. The body may be provided with a

-7-

generally axial channel for receiving a portion of the ligament replacement to be attached to the femur, and the body may be formed to collapse inwardly to secure the replacement ligament portion in the channel as the device is threaded in the femur tunnel.

5 It will be appreciated that, in some embodiments, the naturally occurring extracellular matrix may be cured in such a fashion that the device will provide support structure members for various applications in the orthopedic field. For example, a device for regenerating a meniscus or a portion thereof may be provided with upper and lower panels and a support structure disposed between the
10 upper and lower panels. This support structure may be provided by one or more members of rigid and hardened naturally occurring extracellular matrix. The one or more members may comprise a plurality of generally wedge-shaped members, each member having an upper edge supporting the upper panel and a lower edge supported on the lower panel. In other embodiments, the one or more support members may
15 comprise a lattice of interlocking members, some of which extend radially toward the center of the knee and others of which extend transversely to the radially extending members. These members arranged in the lattice structure define a plurality of spaces between the upper and lower panel. These spaces may be filled with a biological material to promote regeneration of the meniscus. For example, the spaces may be
20 filled with comminuted SIS, a bioactive agent, a biologically derived agent, cells, a biological lubricant, a biocompatible polymer, a biocompatible inorganic material, or combinations thereof. The ECM support structure is believed to provide a framework for meniscus generation. The insertion of the device into a space from which the defective portion of the meniscus has been removed and the attachment of the device
25 to the surrounding tissue places the device such that the meniscus will be regenerated in the space from which the defective portion has been removed. The structural members provided by the rigid and hardened ECM will provide the required support for the joint while regeneration occurs. See U.S. Provisional Patent Application No. 60/305,786, and U.S. Patent Application Serial No. XX/XXX,XXX entitled
30 “Meniscus Regeneration Device and Method” (Attorney Docket No. 265280-71141, DEP-745), filed concurrently herewith, each hereby incorporated by reference.

Thus, one aspect of this disclosure is an orthopedic device for attaching soft tissue such as cartilage, ligament and tendons to bone, the device

-8-

having a head portion configured to engage soft tissue and a body portion configured to engage and attach to the bone, the head portion and body portion being monolithic and formed from naturally occurring extracellular matrix (ECM) cured to be rigid and hardened to facilitate attachment to the bone.

5 Another aspect of this disclosure is an orthopedic tack comprising a head portion and a first body portion formed from naturally occurring extracellular matrix cured to be hard and rigid.

 Yet another aspect of this disclosure is a device for repairing a tear in a cartilaginous surface such as a meniscus, the device comprising strips of naturally
10 occurring extracellular matrix laminated together to form a body portion to be placed down into the tear to extend along the tear, and one or more tacks coupled to the body portion to secure it in the tear, each of the one or more tacks being formed from naturally occurring extracellular matrix.

 Still another aspect of this disclosure is an orthopedic device for
15 attaching or repairing tissue, the device comprising two spaced apart barbs, each barb having a sharpened distal end and a proximal end, and a member connecting the proximal ends of the barbs, the barbs being formed from naturally occurring extracellular matrix

 An additional aspect of this disclosure is a device for anchoring a bone
20 plug in an opening formed in a bone, the device comprising a mass of naturally occurring extracellular matrix formed into a rigid and hardened member configured to be wedged in the opening between the bone plug and the bone.

 Another additional aspect of this disclosure is a method for anchoring a bone plug into an opening formed in a bone for receiving the plug, the method
25 comprising the steps of: providing a member formed into a rigid and hardened mass of naturally occurring extracellular matrix, and placing the member into the opening between the bone plug and the bone.

 Still another aspect of this disclosure is a device for attaching a soft tissue to a bone that has been prepared with an opening to receive the device, the
30 device being formed from a hardened mass of naturally occurring extracellular matrix to form an elongated body to be received in the opening, the body having a channel therein for receiving a portion of the soft tissue, the body being configured to collapse

-9-

inwardly to grip and hold the soft tissue portion in the channel when the body is inserted into the opening.

A further aspect of this disclosure is a tack for driving into a bone, the tack having a proximal head end portion, a distal pointed end portion, and an intermediate body portion, the tack being formed from a hardened mass of naturally occurring extracellular matrix.

In yet another aspect of this disclosure a device is provided for regenerating a meniscus or a portion thereof, the device comprising a wedge-shaped body having an upper panel and a lower panel angularly separated to define an apex portion and a base portion, the panels being formed of a naturally occurring extracellular matrix, and a support structure disposed between the upper panel and lower panel, the support structure comprising one or more members of rigid and hardened naturally occurring extracellular matrix.

One more aspect of this disclosure is an orthopedic device comprising a mass of naturally occurring extracellular matrix or naturally occurring bioremodelable collagenous tissue matrix having a hardness greater than 30 HRD on the Rockwell D Scale.

A final aspect of this disclosure is a composite orthopedic device comprising two connected portions, each portion comprising naturally occurring extracellular matrix material or naturally occurring bioremodelable collagenous tissue matrix, each portion having a hardness and a density, wherein one portion is configured for anchoring the device to native tissue and has a hardness of no less than 50 HRD on the Rockwell D Scale and a density greater than 0.5 g/cc, and the other portion has a different configuration, a different hardness and a different density.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an orthopedic device for attaching soft tissue such as cartilage, ligaments and tendons to bone, the device having a head portion configured to engage the soft tissue and a body portion configured to engage and attach to the bone;

Fig. 2 is a side view of the device of Fig. 1;

Fig. 3 is an end view of the device looking along the lines 3-3 in Fig. 2;

-10-

Fig. 4 is a side view of a device similar to the Fig. 1 device except that it is elongated;

Fig. 5 is a side view of the double-ended tack device;

Fig. 6 is a side view of a double-ended device, one end configured as a
5 tack with barbs and the other end being threaded;

Fig. 7 is an end view of the device shown in Fig. 6 looking along the
lines 7-7;

Fig. 8 is a side view of an elongated tack-like device;

Fig. 9 is a side view of a tack-like device used to hold tissue in an
10 opening formed in a bone;

Fig. 10 is a partially sectioned side view of a tack-like device with a
central core filled with comminuted ECM material;

Fig. 11 is a side view of a tack-like device with a design somewhat
different from the Fig. 1 design;

Fig. 12 is an end view of the Fig. 11 device looking along the lines
12-12 in Fig. 11.
15

Fig. 13 is a perspective view of a device configured to collapse on soft
tissue as the device is inserted into an opening in a bone;

Fig. 14 shows the device of Fig. 13 inserting soft tissue into bone.

Fig. 15 is a top view of the Fig. 16 device looking along the lines 15-
15 in Fig. 16.
20

Fig. 16 is similar to the Fig. 13 device with helical thread segments to
facilitate threading the device into an opening in a bone;

Fig. 17 is a diagrammatical drawing showing how the device of Fig. 6
may be threaded into a bone plug and then how the bone plug may be inserted into the
opening in a bone;
25

Fig. 18 is a sectional view showing the bone plug of Fig. 17 installed
in the bone with the double-ended device of Fig. 6;

Fig. 19 shows a double-ended tack made in accordance with the
present invention used to insert and hold a bone plug into an opening;
30

Fig. 20 shows a sectional view of the bone plug of Fig. 19 after
insertion;

-11-

Fig. 21 shows an elongated and cannulated device which has a generally triangular cross-section with relatively sharp side edges to be driven between a bone plug and an opening in which the plug is inserted.

Fig. 22 is a perspective view of a device similar to the Fig. 21 device except that it has a generally square cross-section with four relatively sharp side edges;

Fig. 23 shows a perspective view of how the devices of Figs. 21 and 22 may be driven to wedge between a bone plug and a bone opening to anchor the bone plug;

Fig. 24 shows a device using barbs made in accordance with the present invention to hold a bone plug into an opening formed in the bone;

Fig. 25 shows an end view of the bone plug of Fig. 24 inserted into the bone opening;

Fig. 26 shows a staple-like device made in accordance with the present invention.

Fig. 27 shows a variation on the staple-like device of Fig. 26;

Fig. 28 shows how a staple-like device may be cut from laminated layers of ECM material;

Fig. 29 shows a laminated body of ECM material held in position by tack-like devices;

Fig. 29(a) shows the device of Fig. 29 without a connecting member between the tacks;

Fig. 30 shows a perspective view of staple-like devices shown in Figs. 26 and 27 used to hold a sheet-like body of ECM material in a tear in a meniscus;

Fig. 31 shows a three-barbed staple device which may be cut from laminated layers of ECM material to have a desired pattern; and

Fig. 32 shows a device similar to Fig. 31, but having a different pattern.

DETAILED DESCRIPTION OF THE DRAWINGS

Figs. 1-3 show an orthopedic device 10 for attaching soft tissue such as cartilage, ligaments, tendons to bone, the device having a head portion 12 configured to engage soft tissue and a body portion 14 configured to engage and attach to the

-12-

bone. The head portion 12 and body portion 14 are illustratively monolithic and formed from naturally occurring extracellular matrix cured to be rigid and hardened to facilitate attachment to the bone. The body portion 14 terminates with a pointed end 16 distal from the head portion 12 to facilitate penetration into the bone. It will be appreciated that the ECM material from which the device 10 is fabricated will be cured to be hardened and toughened such that the device 10 may be driven into bone tissue. The pointed end 16 with its hardness and toughness will facilitate insertion into the bone. To enhance the holding or gripping ability of the device 10, the body portion 14, between the pointed end 16 and the head portion 12, is provided with radially outwardly extending barbs or barb portions 20, 22, which are illustratively inclined toward the head portion. These portions 20, 22 are illustratively defined by machining or forming diametrically opposed flats 24, 26 on the body portion 14, the flats being generally parallel. As best seen in Fig. 3, flats 24 are formed on diametrically opposite sides of the barb portion 20 while the flats 26 are formed on the diametrically opposite sides of the barb portion 22.

The device of Figs. 1-3 and other similar devices disclosed herein may be fabricated by compacting comminuted or shredded naturally occurring ECM material into bar or rod stock by curing the material such that it is very rigid and hardened. The curing may be accomplished by air drying comminuted ECM at room temperature for several days. Comminuted ECM, when dried at room temperature for several days, becomes very tough and hard and can be machined using conventional tools. In one example, a sample of 3 cc of comminuted SIS that has been air dried at room temperature for several days produced a piece of SIS stock that is 7-8 mm in diameter and 2 mm thick, and has a hardness of about 70 HRD on the "Rockwell D" scale. For comparison, polyethylene tests at about 30 HRD, and plexiglass is between 70 and 75 HRD on the "Rockwell D" scale (ASTM D2240, Vol. 0991). Testing was done using an e2000 series durometer from PTC Instruments (model 502D). This durometer conforms to the ASTM D2240 type D standard. The indenter in this type (as in all durometers conforming to ASTM D2240 type D) is a sharp point indenter with a 30 degree included angle and applies a force of 4536 gmf on the sample being tested.

Thus, in an illustrated embodiment an orthopaedic device is formed from comminuted SIS that has been air dried at room temperature for several days.

-13-

The SIS has a hardness of at least 30 HRD on the "D" scale, particularly at least 50 on the "D" scale, more particularly above 60 HRD on the "D" scale, and most particularly about 70 HRD or above on the "D" scale. A hardness of 60-70 is usable in many applications.

5 One sample of comminuted and air-dried SIS was found to have a density of 0.747 +/- 0.059 gm/cc. For comparison, the density of the commercially available RESTORE® product, an ECM laminate, is 0.466 +/- 0.074 gm/cc. And, an ECM product consisting of toughened SIS laminate as described in "Meniscus Regeneration Device and Method" (provisional U.S. Patent Application No. 10 60/305,786 filed on July 16, 2001, and U.S. Patent Application Serial No. XX/XXX,XXX entitled "Meniscus Regeneration Device and Method" (Attorney Docket No. 265280-71141, DEP-745), filed concurrently herewith, has been made with a density of 0.933 +/- 0.061 gm/cc; and an SIS foam can be made as described in U.S. Patent Application Serial No. XX/XXX,XXX entitled "Cartilage Repair and 15 Regeneration Device and Method" (Attorney Docket No. 265280-71145, DEP-752), filed concurrently herewith and hereby incorporated by reference, with a substantially lower density: 0.091 +/- 0.019 gm/cm³; 0.035 +/- 0.012 gm/cm³; or 0.006 +/- 0.002 gm/cm³, for example.

 Drying and hardening may be accelerated by using heat and/or 20 pressure. In an illustrated embodiment, the ECM may be comminuted using a COMITROL machine from Urschel Laboratories (Valparaiso, IN), with a Vericut sealed impeller at 9391 rpm.

 Once the bar stock or rod stock is provided, it may be machined with conventional machine shop equipment to the desired shapes. For example, the device 25 10 may be turned on a lathe or similar equipment to produce the head portion 12 and the body portion 14 with its generally conical barb portions 20, 22. Then, illustratively, the flats 24, 26 may be separately machined such that the conical portions 20, 22 will become more barb-like. It will be appreciated that various barb configurations may be formed on the device 10, for example, by cutting 30 longitudinally extending slots in the body portion 14 to provide more radially outwardly barbs inclined axially toward the head portion 12.

 It has been found that tacks or tack-like devices may be made as shown in Figs. 1-3 such that they can be driven into bone tissue to be securely anchored in

-14-

the tissue. The head portion 12 of such devices 10 may trap soft tissue against the bone surface. It will be appreciated that the head portion 12 may have a larger diameter than proportionately shown in Figs. 1-3 and that the head portion 12 may have a shape other than the circular shape depicted in Figs. 1-3. The head portion 12 itself may be provided with a roughened or barbed surface facing end 16 to attach to the soft tissue being anchored. It will be appreciated that a plurality of devices 10 may be used to secure soft tissue to bone.

Fig. 4 shows a device 30, similar to the device 10 of Figs. 1-3 except that the device 30 is longer. Throughout this description, some corresponding portions of various devices will be identified with the same reference numerals. For example, the device 30 in Fig. 4 has a head portion 12, a body portion 14, and a pointed distal end 16. The device 30 has three barb portions and three sets of flats. The device 30, of course, is to be driven further into the bone structure than the device 10.

Fig. 5 shows a device 36 which is essentially a double-ended tack, each end of which is similar to the device 10 with a common head portion 12, having an illustrative proportionately larger diameter than the head portion 12 of Figs. 1-3. The device 36 of Fig. 5 is provided so that one of its body portions 14 may be inserted into one bone or tissue structure while the other body portion 14 may be inserted into another bone or tissue structure. The diameter of the head portion 12 of the device 36 may be made smaller or larger depending on the attachment application.

Fig. 6 shows a device 40 which is a double-ended device similar to device 36 of Fig. 5 except that one body portion 42 is threaded. Illustratively, the device 40 has another body portion 14 similar to the body portion 14 of Figs. 1-3, with a threaded opposite end portion 42. The head portion 44 of the device 40 may be hexagonal as illustrated or otherwise formed to provide a drive portion for inserting the device. It will be appreciated that a surgeon will be provided with a tubular socket to receive and drivingly engage the head portion 44. The illustrative device 40, which may be cannulated as indicated at broken lines 46 so that the device 40 may be accurately positioned on a K-wire, may optionally have its threaded end provided with diametrically opposed flats 48 (Fig. 7). These flats 48 serve to impede rotation subsequent to implantation.

-15-

One use of the device 40 shown in Fig. 6 and 7 will be discussed in conjunction with inserting bone plugs in connection with Figs. 17 and 18.

Fig. 8 shows a tack 60 with a head portion 62 and an elongated body portion 64 having a distal end 66 that is somewhat sharpened to a point. The tack 60 in Fig. 8 is provided with a pair of longitudinally spaced apart, circumferential ridges 68 between the distal end 66 and the head portion 62. These circumferential ridges 68 serve to lock the device into the surrounding native tissue (i.e., bone).

A device 70 shown in Fig. 10 is similar to devices 10 and 30 except that the proximal body portion 72 including the head 74 is formed with a central bore or opening 76 which may be filled with a mass of comminuted naturally occurring ECM. This central bore space 76 in the device 70 is therefore filled with a biological material to provide a framework for more rapid resorption.

A device 80 is shown in Figs. 11 and 12 to have a head portion 82, a body portion 84 with a distal sharpened end 85. It will be appreciated that the device 80 is similar to the prior devices except that body portion 84 is formed to have three angularly spaced rows of barbs 86 formed at least in part by three angularly spaced apart, longitudinally extending grooves 88 best seen in Fig. 12. It will be appreciated that the barbs 86 are formed to extend radially outwardly from the body portion 84 and inclined axially toward the head portion 82. These barbs 86 and the barbs 20, 22 in the above-described devices 10, 30, 36, 40 and 70 illustratively have an abrupt or sharp edge facing the head portions of the device. It will be appreciated that when the devices are inserted into a bone, the bone will close in on the body portions and these abrupt axially outwardly facing edges of the barbs to secure the devices in the bone. The head portion 82 is shown having three angularly spaced notches 90, which are provided to aid in grasping in delivery of the device. Other configurations are within the scope of this invention.

In accordance with the present invention, a tack or tack-like device may be provided as shown in Fig. 9 without a head portion. Fig. 9 illustrates a device 96, which may be cannulated as indicated at broken lines 98, for insertion in the bone to hold soft tissue. As with devices 10, 14, and 70, device 96 is provided with a plurality of barbs 92, 93, 94. The device as shown in Fig. 9 illustratively may be used, for example, as an interference screw for wedging a bone plug into a bone tunnel, such as for fixing a replacement ligament into the bone tunnel.

-16-

The designs shown in Figs. 1-9, therefore, provide an orthopaedic tack or barbed tack fabricated from naturally occurring ECM that has been cured to be hard and rigid. These devices 10, 30, 36, 40, 60, 70, 80, and 96 may be fabricated from SIS which is cured to be hard and rigid by comminuting the SIS and allowing
5 the comminuted SIS to air dry.

A device 110 is provided for attaching a soft tissue such as a ligament or a tendon to a bone is shown in Fig. 13 -15, the device being formed from a hardened mass of naturally occurring ECM to have an elongated body to be received in an opening formed in the bone. The device 110 has a head portion 112, a central
10 body portion 114 and a distal end 116 all shaped and configured for insertion into a bone opening having a diameter smaller than the largest diameter of the central body portion 114. The device 110 is also provided with a central, longitudinal extending channel 118 extending axially through the device. The illustrative device 110 is further formed with axially and radially extending cut-out or slot 120 which opens
15 from the channel 118 to the exterior of the device 110. It will be appreciated that a piece of soft tissue which may be a ligament, a tendon, or a ligament graft such as an ACL graft, may be inserted axially into the channel 118 to be carried with the device 110 into the bone. While the device 110 is formed from a hardened mass of naturally occurring ECM, it is configured for being forced into an opening prepared in a bone,
20 and to collapse inwardly to grip the soft tissue 122 in the channel 118. The interior of the channel 118 may be provided with a roughened texture or even interior barbs or gripping surfaces to grip the soft tissue 122 more securely as the device 110 collapses radially inwardly. Central body portion 114 is provided with three radially outwardly extending frustoconical engagers 124 which serve to anchor the device 110 in the
25 bone. These engagers 124 have outer surfaces which incline axially toward the head portion 112 and radially outwardly. As the device 110 is driven into the bone opening, these engagers 124 will cause the device to collapse inwardly by bringing the longitudinal walls of the cut-out 120 closer together, reducing the diameter of the channel 118, and holding soft tissue 122 securely within bone 128, as shown in Fig.
30 14. The engagers 124, as illustrated in Fig. 13, have abrupt radially outwardly extending and axially facing surfaces for anchoring the device 110 in the bone opening.

-17-

It will be appreciated that the device 130 may be formed as a threaded device as shown in Fig. 15-16 with helical thread segments replacing the engagers 144 on the central body portion 134. When the device 130 is so threaded, and the head end portion 132 with the hex-shaped cuts 146 is engaged with a socket driver, with the driver end preferably formed on a tube for receiving the soft tissue graft 142, the device 130 can be threaded into a bone opening.

Figs. 17 and 18 show diagrammatically how the device 40 of Fig. 6 and 7 can be used to anchor a bone plug 150 into an opening 152 drilled or otherwise formed in a bone. The threaded body portion 42 of the device 40 may be threaded into a central opening in the bone plug 150 as depicted in Figs. 17 and 18. The opening 152 in the bone may be provided at a diameter which will snugly receive the bone plug 150. The barbed portion (body portion 14) of device 40 is provided to anchor into the bottom of the opening 152. It may be advantageous to provide a central pilot hole 154 in the bottom of the opening 152 to receive and guide the body portion 14 of the device 40. When the bone plug 150 is forced into the opening 152, the structure shown in Fig. 18 will result with the device 40 anchoring the bone plug 150 in the bone.

It is contemplated that the method and device in Figs. 17 and 18 may be used to anchor a cartilage plug 156 into a bone. Essentially, a defect in the cartilage in the surface of a bone, such as on the condyle of a knee, will be removed by forming the opening 152 for receiving the bone plug 150. A cartilage graft 156 will be secured to the bone plug 150 to be used to close the opening 158 made in the cartilage layer 160 in the bone. Thus, the bone plug 150 and the anchoring device 140 may be used to hold a cartilage plug 156 in position in an opening 158 in cartilage 160 such that cartilage plug 156 lies in an essentially contiguous plane with the undamaged surrounding cartilage 168.

Figs. 19 and 20 show how a bone plug 170, which is illustratively formed as a cylindrical bone plug to be anchored into a cylindrical opening 172 in a bone, may be used with the device 36 shown in Fig. 5. The bone opening 172 is provided with a depth sufficient to receive a plug 170, and the bottom 175 of the opening 172 is provided with a pilot hole 174. The plug 170 is prepared with a split end as indicated at 176 and a central pilot opening 178 at bottom surface 179, for facing bottom 175 of opening 172. It will be appreciated that this split end 176 of the

-18-

bone plug 170 will be wedged outwardly by the device 36 so that the outer surface of the bone plug 170 will firmly engage the internal cylindrical surface of the bone opening 172. Fig. 20 shows the device 36 with one of its end portions 14 anchored into the bone in the bottom of the opening 172.

5 Figs. 21 and 22 show devices 180, 190 for use in anchoring bone plugs in openings formed in bones. The devices 180, 190 may be formed from naturally occurring extracellular matrix cured to be rigid and hardened. The device 180 is elongated on a central axis indicated at 182 and may be cannulated on the axis as indicated at 184. Thus, the device 180 may be slid onto a K-wire and located
10 accurately between the outer wall of a bone plug and the inner wall of an opening in which the bone plug is to be anchored. The illustrative device 180 has a generally triangular cross-section providing three longitudinally extending sharpened edges 183 for cutting into the exterior of the bone plug and the interior of the bone opening. Thus, the device 180 may be forced into the space between the exterior of the bone
15 plug and the wall of the opening to extend along the bone plug and wedge the bone plug into firm engagement with the bone opening. The device 190, which is formed about the axis 192 and which may also be cannulated as indicated at 194, is formed to be have a generally square cross-section providing four longitudinally extending side edges 193 to cut into the exterior of the bone plug and the interior of the bone
20 opening.

 In orthopedic surgery work, there are various reasons to insert a bone plug into an opening formed in a bone. While circular bone plugs and circular bone openings are illustrated and discussed herein, it will be appreciated that bone plugs may take various cross-sectional shapes determined by the instruments used to cut the
25 plugs and the particular surgical need. Typically, it is more convenient to drill a cylindrical opening into a bone for receiving a bone plug. To have the bone plug anchored and secured to the wall of the bone opening, it is often necessary to force the bone plug against the wall of the opening in the host bone so that the required bone nourishment and eventual bone ingrowth may take place. This aspect of anchoring
30 bone plugs to bone openings is well known in the orthopedic field. For example, in ACL surgery, it is known to anchor a bone plug harvested on the end of a patellar tendon strip in a tunnel formed upwardly into the femur. Essentially, the patellar tendon is harvested with a bone plug on one end of the strip. The other end may be

-19-

provided with a bone plug as well. This patellar strip is then used as an ACL graft replacement. A tunnel is formed upwardly through a tibial platform into the femur and the ACL graft is secured in place by anchoring one of the bone plugs in the femur and the other of the bone plugs in the tibia. Conventionally, cannulated screws are threaded into the openings to extend alongside the bone plugs. These screws thread into the bone plugs and into the walls of the tunnels to push the plugs into engagement with the tunnel walls. The devices 180, 190 are provided as alternatives to the threaded screws. These devices are pushed into the space between the exterior of a wall of the bone plug and the interior wall of the bone opening. Such a configuration is shown in Fig. 23 where the bone plug 200 is illustrated inserted into the opening or tunnel 202. Again, while the plug 200 is illustrated as having a cylindrical cross-section, it will be appreciated that the plug 200 will have a cross-sectional shape defined by the cutting tools used to remove the plug 200 from its original position. The device 190, however, will be inserted into the space between the plug 200 and the wall of the opening 202 to force the plug against the wall of the opening. It is understood that Fig. 23 shows only a portion of a ACL graft attached to the plug 200.

Referring to Figs. 24 and 25, it will be seen that a bone plug 210 may be secured in a tunnel 212 by barbed anchors 214. Each of these barbed anchors 214 may be formed from hardened naturally occurring ECM to have sharp barbs 216, 218 with a connector portion 220 having a right angle extension 220 to be received into an opening 222 in the bone plug 210. Thus, the barbed anchors 214 may be attached to the bone plug 210 to extend along side the bone plug as it is inserted into the tunnel 212. An ACL graft may be attached to the bone plug 210 as indicated at 224.

The devices are made from ECM that has been cured to a hardness to allow machining. Each of these devices retains its structural integrity for a sufficient period of time to allow the intended orthopaedic fixation, and to permit bone or cartilage ingrowth or repair to begin. Preferably, the devices such as devices 180, 190 and anchors 214 in Figs. 23-25 as well as the devices 10, 30, 36, 40, 60, 70, 80, 96, and 110 are designed to be absorbed into the host tissue, bone, or soft tissue into which they are placed.

Referring to Fig. 26, it will be seen that an orthopedic device 240 for attaching or repairing tissue is illustrated, the device 240 comprising two spaced apart

-20-

barb portions 242, 244, each of which has a proximal end portion 246, a sharpened distal end portion 248, and at least one barb 243. The device 240 has a connecting member 250 extending between the proximal ends 246 to provide a staple-like device. Each of the barb portions 242, 244 may be formed as previously discussed from
5 hardened and rigid naturally occurring ECM. The entire device 240 may be machined from a single block of hardened ECM. Alternatively, barb portions 242, 244 and connecting member 250 may be machined separately, and the connecting member 250 may have its ends inserted into and joined into the proximal end portions 246 of the barb portions as indicated at 252. Connecting member 250 may be affixed to the
10 barb portions 242, 244 in any number of ways, including threading or gluing at insertion 252. The device 240, therefore, may be used as a staple, for example, with the barb portions 242, 244 inserted into the bone and the connecting member 250 holding tissue to the bone. The connecting member 250 may be formed from hardened naturally occurring ECM, flexible ECM, or another material.

15 Fig. 27 shows a device 260 with similar spaced apart barb portions 242, 244 and a connecting member 262 which is hollow and filled with comminuted SIS.

Fig. 28 shows an approach for making a staple or staple-like device 270 having spaced apart barb portions 272, 274 and a connecting member 276. The
20 device 270 contemplates that a plurality of layers of naturally occurring ECM material will be laminated together to be cured by air drying to form a rigid and hardened plate-like body. Then, a laser machine unit 278 will be programmed to cut a pattern which will produce a device 270 from the laminated layers of ECM. It has been found that such laser cutting of several layers of ECM will produce barb
25 portions 272, 274 having cut edges which are sealed and fused together to enhance the attachment capability of the barbs 273. Device 270 may optionally have a plurality of laser cut holes 275, which further fuse together the layers of ECM.

Figs. 31 and 32 show devices 280 and 290, respectively, with different patterns cut from such laminated layers of rigid and hardened naturally occurring
30 ECM. The device 280 is shown having three spaced apart barb portions 282, 284, 286 with a bowed or curved connecting member 288 extending between the proximal ends of the barb portions. The device 290 in Fig. 32 is shown as having three spaced apart barb portions 292, 294 and 296 with a member 298 connecting the proximal

-21-

ends of the barbs. Illustratively, the barb portions 282, 284, 286 and the connecting member 288 may all lie in a common plane. Alternatively, the connecting member 288 may be warped or curved so that the barb portions 282, 284, 286 do not necessarily lie in a common plane. In the device 290, the barb portions 292, 294, 296 initially start out being parallel and lying in a common plane. It will be appreciated that the connecting member 298 may be manipulated by the surgeon to relocate the direction of the barb portions 292, 294, 296.

Fig. 29 shows the staple-like device 310 comprising a pair of spaced apart barb portions 312, 314 formed as discussed above. These barb portions 312, 314 are connected by a connecting member 316 extending between the proximal ends of the barb portions. The device 310 comprises strips of naturally occurring ECM laminated together to form a body portion 320 to be placed down into a tear in a cartilaginous surface such as a meniscus. The barbs 313 hold the body 320 in the tear. It is contemplated that the ends of the body 320 will be attached securely to the barb portions 312, 314. One method of attaching body 320 to barb portions 312, 314 is to insert edges of the body 320 into slots provided in body portions 312, 314. Illustratively, the barbs may be provided with a slit for receiving and gripping and holding the ends of the body 320. It is contemplated that, once the device 310 is fully inserted in the meniscus tear and attached with the barb portions 312, 314, the connecting member 316 and the upper ends of the barb portions may be cut away leaving a structure such as that shown in Fig. 29(a). The body portion 320 may have characteristics different from those of the barb portions 312, 314. For example, the body portion 320 may have a greater porosity or lower density or lower hardness than the barb portions, and may have characteristics similar to those of commercial products like the RESTORE patch, for example. It should be understood that these possible differences in characteristics are provided by way of example only; the illustrated embodiments are not intended to limit the material for the body portion 320.

Fig. 30 shows a device 340 comprising a body such as the body 320 made from laminating layers of naturally occurring ECM together. The ends of the body 320 in the device 340 are attached to the connecting members 250 similar to two devices 240 or 260 as shown in Figs. 26 and 27.

It is anticipated that the hardened ECM devices of the present invention can be combined with one or more bioactive agents (in addition to those already present in naturally occurring ECM), one or more biologically derived agents or substances, one or more cell types, one or more biological lubricants, one or more
5 biocompatible inorganic materials, one or more biocompatible synthetic polymers and one or more biopolymers. Moreover, the hardened ECM devices of the present invention can be combined with devices containing such materials.

“Bioactive agents” include one or more of the following: chemotactic agents; therapeutic agents (e.g., antibiotics, steroidal and non-steroidal analgesics and
10 anti-inflammatories, anti-rejection agents such as immunosuppressants and anti-cancer drugs); various proteins (e.g., short chain peptides, bone morphogenic proteins, glycoprotein and lipoprotein); cell attachment mediators; biologically active ligands; integrin binding sequence; ligands; various growth and/or differentiation agents (e.g., epidermal growth factor, IGF-I, IGF-II, TGF- β I-III, growth and differentiation
15 factors, vascular endothelial growth factors, fibroblast growth factors, platelet derived growth factors, insulin derived growth factor and transforming growth factors, parathyroid hormone, parathyroid hormone related peptide, bFGF; TGF β superfamily factors; BMP-2; BMP-4; BMP-6; BMP-12; sonic hedgehog; GDF5; GDF6; GDF8; PDGF); small molecules that affect the upregulation of specific growth factors;
20 tenascin-C; hyaluronic acid; chondroitin sulfate; fibronectin; decorin; thromboelastin; thrombin-derived peptides; heparin-binding domains; heparin; heparan sulfate; DNA fragments and DNA plasmids. If other such substances have therapeutic value in the orthopaedic field, it is anticipated that at least some of these substances will have use in the present invention, and such substances should be included in the meaning of
25 “bioactive agent” and “bioactive agents” unless expressly limited otherwise.

“Biologically derived agents” include one or more of the following: bone (autograft, allograft, and xenograft) and derivatives of bone; cartilage (autograft, allograft, and xenograft), including, for example, meniscal tissue, and derivatives;
ligament (autograft, allograft, and xenograft) and derivatives; derivatives of intestinal
30 tissue (autograft, allograft, and xenograft), including for example submucosa; derivatives of stomach tissue (autograft, allograft, and xenograft), including for example submucosa; derivatives of bladder tissue (autograft, allograft, and xenograft), including for example submucosa; derivatives of alimentary tissue (autograft,

-23-

allograft, and xenograft), including for example submucosa; derivatives of respiratory tissue (autograft, allograft, and xenograft), including for example submucosa; derivatives of genital tissue (autograft, allograft, and xenograft), including for example submucosa; derivatives of liver tissue (autograft, allograft, and xenograft), including for example liver basement membrane; derivatives of skin tissue; platelet rich plasma (PRP), platelet poor plasma, bone marrow aspirate, demineralized bone matrix, insulin derived growth factor, whole blood, fibrin and blood clot. Purified ECM and other collagen sources are also intended to be included within “biologically derived agents.” If other such substances have therapeutic value in the orthopaedic field, it is anticipated that at least some of these substances will have use in the present invention, and such substances should be included in the meaning of “biologically derived agent” and “biologically derived agents” unless expressly limited otherwise.

“Biologically derived agents” also include bioremodelable collagenous tissue matrices. The expressions “bioremodelable collagenous tissue matrix” and “naturally occurring bioremodelable collagenous tissue matrix” include matrices derived from native tissue selected from the group consisting of skin, artery, vein, pericardium, heart valve, dura mater, ligament, bone, cartilage, bladder, liver, stomach, fascia and intestine, tendon, whatever the source. Although “naturally occurring bioremodelable collagenous tissue matrix” is intended to refer to matrix material that has been cleaned, processed, sterilized, and optionally crosslinked, it is not within the definition of a naturally occurring bioremodelable collagenous tissue matrix to purify the natural fibers and reform a matrix material from purified natural fibers. The term “bioremodelable collagenous tissue matrices” includes “extracellular matrices” within its definition.

“Cells” include one or more of the following: chondrocytes; fibrochondrocytes; osteocytes; osteoblasts; osteoclasts; synoviocytes; bone marrow cells; mesenchymal cells; stromal cells; stem cells; embryonic stem cells; precursor cells derived from adipose tissue; peripheral blood progenitor cells; stem cells isolated from adult tissue; genetically transformed cells; a combination of chondrocytes and other cells; a combination of osteocytes and other cells; a combination of synoviocytes and other cells; a combination of bone marrow cells and other cells; a combination of mesenchymal cells and other cells; a combination of stromal cells and

-24-

other cells; a combination of stem cells and other cells; a combination of embryonic stem cells and other cells; a combination of precursor cells isolated from adult tissue and other cells; a combination of peripheral blood progenitor cells and other cells; a combination of stem cells isolated from adult tissue and other cells; and a combination of genetically transformed cells and other cells. If other cells are found to have therapeutic value in the orthopaedic field, it is anticipated that at least some of these cells will have use in the present invention, and such cells should be included within the meaning of "cell" and "cells" unless expressly limited otherwise. Illustratively, in one example of embodiments that are to be seeded with living cells such as chondrocytes, a sterilized implant may be subsequently seeded with living cells and packaged in an appropriate medium for the cell type used. For example, a cell culture medium comprising Dulbecco's Modified Eagles Medium (DMEM) can be used with standard additives such as non-essential amino acids, glucose, ascorbic acid, sodium pyrovate, fungicides, antibiotics, etc., in concentrations deemed appropriate for cell type, shipping conditions, etc.

"Biological lubricants" include: hyaluronic acid and its salts, such as sodium hyaluronate; glycosaminoglycans such as dermatan sulfate, heparan sulfate, chondroitin sulfate and keratan sulfate; synovial fluid and components of synovial fluid, including mucinous glycoproteins (e.g., lubricin), tribonectins, articular cartilage superficial zone proteins, surface-active phospholipids, lubricating glycoproteins I, II; vitronectin; and rooster comb hyaluronate. "Biological lubricant" is also intended to include commercial products such as ARTHREASETM high molecular weight sodium hyaluronate, available in Europe from DePuy International, Ltd. of Leeds, England, and manufactured by Bio-Technology General (Israel) Ltd., of Rehovot, Israel; SYNVIS[®] Hylan G-F 20, manufactured by Biomatrix, Inc., of Ridgefield, New Jersey and distributed by Wyeth-Ayerst Pharmaceuticals of Philadelphia, Pennsylvania; HYLAGAN[®] sodium hyaluronate, available from Sanofi-Synthelabo, Inc., of New York, New York, manufactured by FIDIA S.p.A., of Padua, Italy; and HEALON[®] sodium hyaluronate, available from Pharmacia Corporation of Peapack, New Jersey in concentrations of 1%, 1.4% and 2.3% (for ophthalmologic uses). If other such substances have therapeutic value in the orthopaedic field, it is anticipated that at least some of these substances will have use

-25-

in the present invention, and such substances should be included in the meaning of “biological lubricant” and “biological lubricants” unless expressly limited otherwise.

“Biocompatible polymers” is intended to include both synthetic polymers and biopolymers (e.g., collagen). Examples of biocompatible polymers include: polyesters of [alpha]-hydroxycarboxylic acids, such as poly(L-lactide) (PLLA) and polyglycolide (PGA); poly-p-dioxanone (PDS); polycaprolactone (PCL); polyvinyl alcohol (PVA); polyethylene oxide (PEO); polymers disclosed in United States Patents. Nos. 6,333,029 and 6,355,699; and any other bioresorbable and biocompatible polymer, co-polymer or mixture of polymers or co-polymers that are utilized in the construction of prosthetic implants. In addition, as new biocompatible, bioresorbable materials are developed, it is expected that at least some of them will be useful materials from which the anchors may be made. It should be understood that the above materials are identified by way of example only, and the present invention is not limited to any particular material unless expressly called for in the claims.

“Biocompatible inorganic materials” include materials such as hydroxyapatite, all calcium phosphates, alpha-tricalcium phosphate, beta-tricalcium phosphate, calcium carbonate, barium carbonate, calcium sulfate, barium sulfate, polymorphs of calcium phosphate, sintered and non-sintered ceramic particles, and combinations of such materials. If other such substances have therapeutic value in the orthopaedic field, it is anticipated that at least some of these substances will have use in the present invention, and such substances should be included in the meaning of “biocompatible inorganic material” and “biocompatible inorganic materials” unless expressly limited otherwise.

It is expected that various combinations of bioactive agents, biologically derived agents, cells, biological lubricants, biocompatible inorganic materials, biocompatible polymers can be used with the hardened ECM devices of the present invention.

It is expected that standard disinfection (e.g., .15% peracetic acid in 20% ethanol) and sterilization techniques (e.g., electron beam or gamma irradiation) may be used with the products of the present invention. Although it is anticipated that some of the identified additives could be added to the devices prior to terminal sterilization, other additives, such as cells, for example, would be cultured on

-26-

previously sterilized devices. In addition, some bioactive agents could be added to the devices in the operating room, such as an autograft of PRP for example.

The hardened ECM devices of the present invention can also be combined with other devices that include naturally occurring ECM, and it is expected
5 that the hardened ECM devices can be combined with purified ECM and commercially available collagen materials and/or with devices that contain purified ECM and commercially available collagen materials.

Illustrative applications for the hardened ECM devices of the present invention, and potential materials to be incorporated with the hardened ECM devices
10 of the present invention, are illustrated in the following U.S. Patent Applications, filed concurrently herewith and incorporated by reference herein in their entireties: Serial No. XX/XXX,XXX entitled "Meniscus Regeneration Device and Method" (Attorney Docket No. 265280-71141, DEP-745); Serial No. XX/XXX,XXX entitled "Cartilage Repair Apparatus and Method" (Attorney Docket No. 265280-71143, DEP-749);
15 Serial No. XX/XXX,XXX entitled "Unitary Surgical Device and Method" (Attorney Docket No. DEP-750); Serial No. XX/XXX,XXX entitled "Hybrid Biologic/Synthetic Porous Extracellular Matrix Scaffolds" (Attorney Docket No. 265280-71144, DEP-751); Serial No. XX/XXX,XXX entitled "Cartilage Repair and Regeneration Device and Method" (Attorney Docket No. 265280-71145, DEP-752); and Serial No.
20 XX/XXX,XXX entitled "Cartilage Repair and Regeneration Device and Method" (Attorney Docket No. 265280-71145, DEP-752). Thus, implants can be made as composites of materials of different characteristics.

Although the invention has been described in detail with reference to certain preferred embodiments, variations and modifications exist within the scope
25 and spirit of the invention as described and defined in the following claims.

-27-

CLAIMS:

1. An orthopedic device for attaching soft tissue such as cartilage, ligament and tendons to bone, the device having a head portion configured to engage soft tissue and a body portion configured to engage and attach to the bone, the head portion and body portion being monolithic and formed from naturally occurring extracellular matrix (ECM) cured to be rigid and hardened to facilitate attachment to the bone.
2. The device of claim 1 in which the body portion terminates with a pointed end distal from the head portion to facilitate penetration into the bone.
3. The device of claim 2 in which the body portion between the pointed end and the head portion is formed with radially outwardly extending barbs.
4. The device of claim 3 in which the barbs are inclined toward the head portion.
5. The device of claim 4 in which the body portion is provided with diametrically opposed flats extending therealong, the flats being generally parallel.
6. The device of claim 5 in which the device is formed by machining a mass of the cured matrix to define the head portion and body portion.
7. The device of claim 1 in which the cured ECM is cured by air drying.
8. The device of claim 1 in which the cured ECM is dried at room temperature.
9. The device of claim 1 in which the cured ECM is dried with pressure.
10. The device of claim 1 in which the cured ECM is dried with heat.
11. The device of claim 10 in which the cured ECM is dried with pressure.
12. The device of claim 1 in which the cured ECM has a hardness of at least 30 on the "D" scale.

-28-

13. The device of claim 1 in which the cured ECM has a hardness of at least 60 on the "D" scale.

14. The device of claim 1 in which the cured ECM has a hardness of at least 70 on the "D" scale.

5 15. The device of claim 1 in which the body portion is formed with an outer shell defining a central core space, and comprising a biological material to provide a framework for tissue regeneration disposed in the space.

16. The device of claim 15 in which the biological material is comminuted naturally occurring ECM.

10 17. The device of claim 16 in which the cured ECM is SIS and the comminuted ECM is SIS.

18. The device of claim 1 in which the head portion and body portion are formed about a central axis and concentrically and axially cannulated to receive a guide member.

15 19. The device of claim 1 in which the head portion and body portion are formed about a central longitudinal axis and a second body portion is provided to extend axially away from the head portion in a direction opposite to the first mentioned body portion.

20 20. The device of claim 19 in which the second body portion is threaded.

21. The device of claim 20 in which the second body portion is provided with diametrically opposed, longitudinally extending generally parallel flats in the portion threaded.

25 22. The device of claim 21 in which the first mentioned body portion is provided with outwardly extending barbs.

23. The device of claim 22 in which the barbs extend radially outwardly and axially toward the head portion.

24. The device of claim 23 in which the first mentioned body portion terminates with a pointed end distal from the head portion.

30 25. An orthopedic tack comprising a head portion and a first body portion formed from naturally occurring extracellular matrix cured to be hard and rigid.

-29-

26. The tack of claim 25 in which the extracellular matrix is SIS formed into a three-dimensional mass and cured by drying.

27. The tack of claim 26 in which the matrix is cured by air drying.

28. The tack of claim 27 in which the head portion and first body portion are formed by machining their shapes from the cured mass of SIS.

29. The tack of claim 25 in which the first body portion and head portion are formed about a central axis, and the first body portion terminates in a pointed end distal to the head portion.

30. The tack of claim 29 including a second body portion extending away from the head portion in an axial direction opposite to the first body portion.

31. The tack of claim 30 in which at least one of the body portions is provided with outwardly extending barbs.

32. The tack of claim 31 in which the barbs extend radially outwardly and axially toward the head portion.

33. The tack of claim 30 in which at least one of the body portions is threaded.

34. The tack of claim 31 in which the at least one body portion is formed with diametrically opposed, longitudinally extending generally parallel flats.

35. The tack of claim 33 in which the threaded body portion is formed with diametrically opposed, longitudinally extending generally parallel flats.

36. The tack of claim 25 in which the first body portion is formed to have a central bore, and comprising a biological material to provide a framework for regeneration of tissue disposed in the bore.

37. The tack of claim 25 in which the matrix is SIS and in which the first body portion is formed with a core space filled with comminuted SIS.

38. The tack of claim 37 in which the first body portion is further formed to have a distal end portion terminating with a pointed end, the distal end portion being provided with outwardly extending barbs.

39. A device for repairing a tear in a cartilaginous surface such as a meniscus, the device comprising strips of naturally occurring extracellular matrix laminated together to form a body portion to be placed down into the tear to extend along the tear, and one or more tacks coupled to the body portion to secure it in the

-30-

tear, each of the one or more tacks being formed from naturally occurring extracellular matrix.

40. The device of claim 39 in which the body portion has an upper edge, a lower edge and opposite end edges, the one or more tacks comprising a tack
5 coupled to each of the opposite end edges of the body portion.

41. The device of claim 40 in which each tack extends along the opposite end edge to which it is coupled.

42. The device of claim 41 in which the body portion is coupled to each tack along its length.

10 43. The device of claim 42 in which each tack is provided with barbs which extend radially outwardly and axially toward the upper edge.

44. The device of claim 39 comprising a member connecting the one or more tacks, the connecting member being formed from naturally occurring extracellular matrix.

15 45. The device of claim 44 in which the connecting member is detachable by a surgeon after the body portion and tacks are inserted into the tear.

46. The device of claim 39 in which the ECM is SIS that is cured to be hard and rigid.

20 47. The device of claim 46 in which the ECM is SIS is dried by air drying at room temperature.

48. The device of claim 46 in which the SIS has a hardness of at least 30 on the "D" scale.

49. The device of claim 48 in which the SIS has a hardness of at least 60 on the "D" scale.

25 50. The device of claim 49 in which the SIS has a hardness of at least 70 on the "D" scale.

51. The device of claim 39 in which the one or more tacks comprise a pair of tacks each having a pointed distal end and a proximal end and a connecting member coupled between the proximal ends of the tacks, the connecting
30 member being coupled to the body portion.

52. The device of claim 51 in which the connecting member extends transverse to the body portion, the connecting member having a central portion coupled to the body portion.

-31-

53. An orthopedic device for attaching or repairing tissue, the device comprising two spaced apart barbs, each barb having a sharpened distal end and a proximal end, and a member connecting the proximal ends of the barbs, the barbs being formed from naturally occurring extracellular matrix.

5 54. The device of claim 53 in which the connecting member is formed of the naturally occurring extracellular matrix.

55. The device of claim 54 in which the matrix is SIS.

56. The device of claim 53 in which the connecting member and the barbs are formed from layers of naturally occurring extracellular matrix laminated together and cured to form a rigid and hardened sheet-like body, the barbs and the
10 connecting member being cut from the body.

57. The device of claim 56 in which the barbs and connecting member are cut by laser machining a pattern on the sheet-like body.

58. The device of claim 57 in which the barbs have edges formed
15 by fusing the layers together in the laser machining.

59. The device of claim 58 further having a plurality of laser-cut holes.

60. The device of claim 56 comprising a third barb cut from the sheet-like body and having a sharpened distal end and a proximal end formed from
20 the sheet-like body, the connecting member being cut from the sheet-like body to connect to the proximal end of the third barb.

61. The device of claim 60 in which the three barbs lie in generally the same plane.

62. The device of claim 53 in which the barbs and the connecting
25 member are machined from a single piece of extracellular matrix.

63. The device of claim 53 in which the barbs are machined from extracellular matrix cured to be hard and rigid and each barb has a proximal end portion configured to receive an end of the connecting member.

64. The device of claim 63 in which the connecting member is
30 machined from extracellular matrix.

65. A device for anchoring a bone plug in an opening formed in a bone, the device comprising a mass of naturally occurring extracellular matrix formed

-32-

into a rigid and hardened member configured to be wedged in the opening between the bone plug and the bone.

66. The device of claim 65 in which the member has a body portion formed with outwardly extending barbs to dig into the bone plug and bone.

5 67. The device of claim 66 in which the member is provided with a connecting portion to extend into the bone plug.

68. The device claim 65 in which the member is elongated to extend axially along side the bone plug, the member having a plurality of radially outwardly and longitudinally extending fins to dig into the bone plug and bone.

10 69. The device of claim 68 in which the elongated member is cannulated longitudinally to be sleeved over an elongated guide member such as a K-wire.

70. The device of claim 65 in which the matrix is SIS.

15 71. The device of claim 70 in which the SIS is cured by drying at room temperature to form the rigid and hardened member.

72. The device of claim 70 in which the SIS has a hardness of about 70 on the "D" scale.

73. The device of claim 65 in which the member is formed in the shape of a screw to be threaded into the opening between the bone plug and bone.

20 74. A method for anchoring a bone plug into an opening formed in a bone for receiving the plug, the method comprising the steps of:

providing a member formed into a rigid and hardened mass of naturally occurring extracellular matrix, and

25 placing the member into the opening between the bone plug and the bone.

75. The method of claim 74 in which the member is provided with barbs that dig into the bone plug and bone.

76. The method of claim 74 in which the member is elongated to extend alongside the bone plug to be wedged between the bone plug and bone.

30 77. The method of claim 74 in which the member is elongated and threaded to provide a screw to be threaded between the bone plug and the bone.

78. The method of claim 74 in which the bone opening is formed with cylindrical wall and a bottom to receive a cylindrical bone plug, and the placing

-33-

step comprising placing the member in the opening to engage the bone plug and the bone.

79. The method of claim 78 in the member is provided as a double-ended tack, one end of which extends into the bottom of the opening and the other end
5 of which extends into a bottom surface of the bone plug.

80. The method of claim 79 in which the bottom surface of the bone plug is formed to have a split end, and the placing step further comprises forcing the bone plug split end over the other end of the tack to wedge the bone plug outwardly against the bone opening wall.

10 81. The method of claim 80 in which the split end of the bone plug is provided with a central pilot hole for receiving the other end of the tack.

82. The method of claim 74 in which the matrix is SIS.

83. The method of claim 82 in which the SIS is cured by drying at room temperature to form the rigid and hardened member.

15 84. The device of claim 83 in which the SIS has a hardness of about 70 on the "D" scale.

85. A device for attaching a soft tissue to a bone that has been prepared with an opening to receive the device, the device being formed from a hardened mass of naturally occurring extracellular matrix to form an elongated body
20 to be received in the opening, the body having a channel therein for receiving a portion of the soft tissue, the body being configured to collapse inwardly to grip and hold the soft tissue portion in the channel when the body is inserted into the opening.

86. The device of claim 85 in which the body is elongated and formed generally about an axis, the body having a threaded outer surface to
25 accomplish threading the device into the bone opening.

87. The device of claim 86 in which the body is formed such that the channel is a central bore extending through at least a portion of the body, the body having an axially extending slot opening between the channel and the outer surface to accommodate the inward collapse of the device as the device is threaded into the bone
30 opening.

88. The device of claim 85 in which the matrix is SIS.

-34-

89. The device of claim 88 in which the mass of SIS is dried to be hardened and then machined to have external threads for threadedly engaging the bone opening.

5 90. The device of claim 89 in which the device is provided with an axial slot to accommodate the inward collapse of the device as it is threaded into the bone opening.

91. The device of claim 85 in which the body is elongated and formed generally about an axis, the body having an outer surface providing radially outwardly extending engagers to engage into bone.

10 92. The device of claim 91 in which the engagers are formed to have axially and radially inclined surfaces that force the device to collapse inwardly.

93. A tack for driving into a bone, the tack having a proximal head end portion, a distal pointed end portion, and an intermediate body portion, the tack being formed from a hardened mass of naturally occurring extracellular matrix.

15 94. The tack of claim 93 in which the intermediate body portion is formed with barbs extending radially outwardly and axially toward the head end portions.

95. The tack of claim 94 in which the barbs are each formed in part by forming flats on the intermediate body portion.

20 96. The device of claim 93 in which the matrix is SIS.

97. The device of claim 96 in which the SIS is comminuted.

98. The device of claim 97 in which the SIS is cured by air drying.

99. The device of claim 97 in which the SIS is dried at room temperature.

25 100. The device of claim 97 in which the SIS is dried with pressure.

101. The device of claim 97 in which the SIS is dried with heat.

102. The device of claim 101 in which the SIS is dried with pressure.

30 103. The device of claim 97 in which the SIS has a hardness of at least 30 on the "D" scale.

104. The device of claim 103 in which the SIS has a hardness of at least 50 on the "D" scale.

-35-

105. The device of claim 104 in which the SIS has a hardness of at least 60 on the "D" scale.

106. The device of claim 70 in which the SIS has a hardness of at least 70 on the "D" scale.

5 107. The device of claim 96 in which the SIS has a hardness of at least 30 on the "D" scale.

108. The device of claim 96 in which the SIS has a hardness of at least 60 on the "D" scale.

10 109. The device of claim 96 in which the SIS has a hardness of at least 70 on the "D" scale.

110. A device for regenerating a meniscus or a portion thereof, the device comprising

a wedge-shaped body having an upper panel and a lower panel angularly separated to define an apex portion and a base portion, the panels being
15 formed of a naturally occurring extracellular matrix, and

a support structure disposed between the upper panel and lower panel, the support structure comprising one or more members of rigid and hardened naturally occurring extracellular matrix.

20 111. The device of claim 110 in which the one or more members comprise a plurality of generally wedge shaped members, each member having an upper edge supporting the upper panel and a lower edge supported on the lower panel.

112. The device of claim 110 in which the one or more members comprise a plurality of wafer-like members, each member having a generally wedge shape corresponding to a meniscus section taken from a natural meniscus in a plane
25 extending radially outwardly and axially along the tibial axis, the plurality of members being disposed in a side-by-side relation about the circumference of the meniscus being generated between the upper and lower panels, each member having an upper edge supporting the upper panel and a lower edge resting on the lower panel.

30 113. The device of claim 112 in which the plurality of wafer-like members are connected together to allow some individual movement of each member.

114. The device of claim 112 in which each of the members is provided with an opening therethrough, and the device further comprises a connecting member extending through the openings in the members.

-36-

115. The device of claim 110 in which the extracellular matrix is rigid and hardened SIS.

116. The device of claim 110 in which the at least one or more members comprises a lattice of interlocking first members extending generally
5 radially toward the center of the knee and second members extending transversely to the first members, the first and second members defining a plurality of open spaces between the upper panel and the lower panel, and the device further comprises a biological material to promote regeneration of the meniscus disposed in the open spaces.

10 117. An orthopedic device comprising a mass of naturally occurring extracellular matrix having a hardness greater than 30 HRD on the Rockwell D Scale.

118. The orthopedic device of claim 117 wherein the mass of naturally occurring extracellular matrix has a hardness of at least 60 HRD on the Rockwell D scale.

15 119. The orthopedic device of claim 117 wherein the mass of naturally occurring extracellular matrix has a hardness of at least 70 HRD on the Rockwell D scale.

120. The orthopedic device of 117 wherein the mass of naturally occurring extracellular matrix has a density greater than 0.5 g/cc.

20 121. The orthopedic device of claim 117 wherein the mass of naturally occurring extracellular matrix has a density greater than 0.7 g/cc.

122. The orthopedic device of claim 117 wherein the device is a composite with a material selected from the group consisting of:

- 25 a bioactive agent;
- a biologically derived agent;
- a biological lubricant;
- a biocompatible polymer;
- a biocompatible inorganic material;
- cells;
- 30 chondrocytes;
- osteocytes;
- synoviocytes;

-37-

a naturally occurring ECM that has a hardness less than 70 HRD on the Rockwell D Scale;

a naturally occurring ECM having a density less than 0.7 g/cc;

a mat including a nonwoven naturally occurring ECM;

5 braided naturally occurring ECM;

an ECM foam;

an ECM laminate;

an ECM woven;

a biologically absorbable polymer laminate;

10 a biologically absorbable polymer foam;

a biologically absorbable polymer woven material; and

a mat including a nonwoven naturally occurring biologically absorbable polymer.

123. The orthopedic device of claim 117 wherein the device
15 comprises a configuration selected from the group consisting of:

an orthopedic tack comprising a monolithic head portion and a body portion;

an anchor for attaching soft tissue to bone, the device having a portion configured to engage soft tissue and an integral portion configured to engage bone;

20 an anchor comprising at least two spaced apart barbs, each barb having a sharpened distal end and a proximal end, the device further comprising a member connecting the proximal ends of the barbs;

an anchor comprising at least two spaced apart barbs and an integral member connecting the two barbs;

25 an anchor for anchoring a bone plug in an opening formed in bone, the naturally occurring extracellular matrix being configured to be wedged between the bone plug and the bone;

an anchor comprising a body having a channel therein, the body being configured to collapse inwardly under compression;

30 an outer shell portion and an inner portion surrounded by the shell, wherein the outer shell portion has a hardness greater than 30 HRD on the Rockwell D Scale and the inner portion has a hardness less than 70 HRD on the Rockwell D Scale; and

-38-

a wedge-shaped body having an upper panel and a lower panel angularly separated to define an apex portion and a base portion, the panels being formed of a naturally occurring extracellular matrix.

124. The orthopedic device of claim 123 wherein the device
5 comprises a composite with a material selected from the group consisting of:
a bioactive agent;
a biologically derived agent;
a biological lubricant;
a biocompatible polymer;
10 a biocompatible inorganic material;
cells;
chondrocytes;
osteocytes;
synoviocytes;
15 a naturally occurring extracellular matrix that has a hardness less than
70 HRD on the Rockwell D Scale;
a naturally occurring extracellular matrix having a density less than 0.7
g/cc;
a mat of nonwoven naturally occurring extracellular matrix;
20 an ECM foam;
an ECM laminate;
an ECM woven;
a biologically absorbable polymer laminate;
a biologically absorbable polymer foam;
25 a biologically absorbable polymer woven; and
a mat of nonwoven naturally occurring biologically absorbable
polymer.

125. The orthopedic device of claim 124 wherein the mass of
naturally occurring extracellular matrix has a hardness of at least 60 HRD on the
30 Rockwell D Scale.

126. The orthopedic device of 125 wherein the mass of naturally
occurring extracellular matrix has a hardness of at least 70 HRD on the Rockwell D
scale.

-39-

127. A composite orthopedic device comprising two connected portions, each portion comprising naturally occurring extracellular matrix material, each portion having a hardness and a density, wherein one portion is configured for anchoring the device to native tissue and has a hardness of no less than 50 HRD on the Rockwell D Scale and a density greater than 0.5 g/cc, and the other portion has a different configuration, a different hardness and a different density.

128. The composite orthopedic device of claim 127 wherein at least one of the portions has a density of no less than 0.7 g/cc.

129. The composite device of claim 127 wherein at least one of the portions further comprises a material selected from the group consisting of:

- a bioactive agent;
- a biologically derived agent;
- a biological lubricant;
- a biocompatible polymer;
- a biocompatible inorganic material;
- cells;
- chondrocytes;
- osteocytes;
- synoviocytes;
- a mat including nonwoven naturally occurring extracellular matrix;
- an ECM foam;
- an ECM laminate;
- an ECM woven;
- a toughened ECM material;
- a biologically absorbable polymer laminate;
- a biologically absorbable polymer foam;
- a biologically absorbable polymer woven; and
- a mat including nonwoven naturally occurring biologically absorbable polymer.

130. The composite device of claim 127 wherein the device comprises a configuration selected from the group consisting of:

- an orthopedic tack comprising a monolithic head portion and a body portion;

-40-

an anchor for attaching soft tissue to bone, the device having a portion configured to engage soft tissue and an integral portion configured to engage bone;

an anchor comprising at least two spaced apart barbs, each barb having a sharpened distal end and a proximal end, the device further comprising a member
5 connecting the proximal ends of the barbs;

an anchor comprising at least two spaced apart barbs and an integral member connecting the two barbs;

an anchor for anchoring a bone plug in an opening formed in bone, at least part of the device being configured to be wedged between the bone plug and the
10 bone;

an anchor comprising a body having a channel therein, the body being configured to collapse inwardly under compression;

a meniscal repair device comprising a pair of barbs and a sheet of naturally occurring extracellular matrix material extending between the barbs;

an outer shell portion and an inner portion surrounded by the shell, wherein the outer shell portion has a density greater than the inner portion; and
15

a wedge-shaped body having an upper panel and a lower panel angularly separated to define an apex portion and a base portion, the panels being formed of a naturally occurring extracellular matrix.

20 131. An orthopedic device comprising bioremodelable collageneous tissue matrix having a hardness greater than 30 HRD on the Rockwell D Scale.

132. The orthopedic device of claim 131 wherein the bioremodelable collageneous tissue matrix has a hardness of at least 60 HRD on the Rockwell D scale.

25 133. The orthopedic device of claim 131 wherein the bioremodelable collageneous tissue matrix has a hardness of at least 70 HRD on the Rockwell D scale.

134. The orthopedic device of claim 131 wherein the bioremodelable collageneous tissue matrix has a density greater than 0.5 g/cc.

30 135. The orthopedic device of claim 131 wherein the bioremodelable collageneous tissue matrix has a density greater than 0.7 g/cc.

136. The orthopedic device of claim 131 wherein the device comprises a composite with a material selected from the group consisting of:

-41-

- a bioactive agent;
- a biologically derived agent;
- a biological lubricant;
- a biocompatible polymer;
- 5 a biocompatible inorganic material;
- cells;
- chondrocytes;
- osteocytes;
- synoviocytes;
- 10 a naturally occurring bioremodelable collagenous tissue matrix that has a hardness less than 70 HRD on the Rockwell D Scale;
- a naturally occurring bioremodelable collagenous tissue matrix having a density less than 0.7 g/cc;
- a mat including a non-woven naturally occurring bioremodelable
- 15 collagenous tissue matrix;
- braided naturally occurring bioremodelable collagenous tissue matrix;
- a foam comprising bioremodelable collagenous tissue matrix;
- a laminate comprising bioremodelable collagenous tissue matrix;
- a woven material comprising bioremodelable collagenous tissue
- 20 matrix;
- a biologically absorbable polymer laminate;
- a biologically absorbable polymer foam;
- a biologically absorbable polymer woven material; and
- a mat including a non-woven biologically absorbable polymer.
- 25 137. The orthopedic device of claim 131 wherein the device comprises a configuration selected from the group consisting of:
- an orthopedic tack comprising a monolithic head portion and a body portion;
- an anchor for attaching soft tissue to bone, the device having a portion
- 30 configured to engage soft tissue and an integral portion configured to engage bone;
- an anchor comprising at least two spaced apart barbs, each barb having a sharpened distal end and a proximal end, the device further comprising a member connecting the proximal ends of the barbs;

-42-

an anchor comprising at least two spaced apart barbs and an integral member connecting the two barbs;

an anchor for anchoring a bone plug in an opening formed in bone, the bioremodelable collageneous tissue matrix being configured to be wedged between
5 the bone plug and the bone;

an anchor comprising a body having a channel therein, the body being configured to collapse inwardly under compression;

an outer shell portion and an inner portion surrounded by the shell, wherein the outer shell portion has a hardness greater than 50 HRD on the Rockwell
10 D Scale and the inner portion has a hardness less than 70 HRD on the Rockwell D Scale; and

a wedge-shaped body having an upper panel and a lower panel angularly separated to define an apex portion and a base portion, the panels being formed of a naturally occurring bioremodelable collageneous tissue matrix.

15 138. The orthopedic device of claim 137 wherein the device comprises a composite with a material selected from the group consisting of:

- a bioactive agent;
- a biologically derived agent;
- a biological lubricant;
- 20 a biocompatible polymer;
- a biocompatible inorganic material;
- cells;
- chondrocytes;
- osteocytes;
- 25 synoviocytes;
- a naturally occurring bioremodelable collageneous tissue matrix that has a hardness less than 70 HRD on the Rockwell D Scale;
- a naturally occurring bioremodelable collageneous tissue matrix having a density less than 0.7 g/cc;
- 30 a mat of nonwoven naturally occurring bioremodelable collageneous tissue matrix;
- a foam comprising bioremodelable collageneous tissue matrix;
- a laminate comprising bioremodelable collageneous tissue matrix;

-43-

a woven material comprising bioremodelable collageneous tissue matrix;

a biologically absorbable polymer laminate;

a biologically absorbable polymer foam;

5 a biologically absorbable polymer woven; and

a mat of non-woven biologically absorbable polymer.

139. The orthopedic device of claim 138 wherein the bioremodelable collageneous tissue matrix has a hardness of at least 50 HRD on the Rockwell D Scale.

10 140. The orthopedic device of claim 137 wherein the bioremodelable collageneous tissue matrix has a hardness of at least 70 HRD on the Rockwell D scale.

141. A composite orthopedic device comprising two connected portions, each portion comprising naturally occurring bioremodelable collageneous tissue matrix, each portion having a hardness and a density, wherein one portion has a hardness of no less than 50 HRD on the Rockwell D Scale and a density greater than 0.5 g/cc, and the other portion has a different hardness and a different density.

142. The composite orthopedic device of claim 141 wherein at least one of the portions has a density of no less than 0.7 g/cc.

20 143. The composite device of claim 141 wherein at least one of the portions comprises a material selected from the group consisting of:

a bioactive agent;

a biologically derived agent;

a biological lubricant;

25 a biocompatible polymer;

a biocompatible inorganic material;

cells;

chondrocytes;

osteocytes;

30 synoviocytes;

a mat including non-woven naturally occurring bioremodelable collageneous tissue matrix;

a foam comprising bioremodelable collageneous tissue matrix;

-44-

a laminate comprising bioremodelable collagenous tissue matrix;
a woven material comprising bioremodelable collagenous tissue
matrix;

- 5 a toughened bioremodelable collagenous tissue matrix material;
a biologically absorbable polymer laminate;
a biologically absorbable polymer foam;
a biologically absorbable polymer woven; and
a mat including non-woven biologically absorbable polymer.

144. The composite device of claim 141 wherein the device
10 comprises a configuration selected from the group consisting of:

an orthopedic tack comprising a monolithic head portion and a body
portion;

an anchor for attaching soft tissue to bone, the device having a portion
configured to engage soft tissue and an integral portion configured to engage bone;

15 an anchor comprising at least two spaced apart barbs, each barb having
a sharpened distal end and a proximal end, the device further comprising a member
connecting the proximal ends of the barbs;

an anchor comprising at least two spaced apart barbs and an integral
member connecting the two barbs;

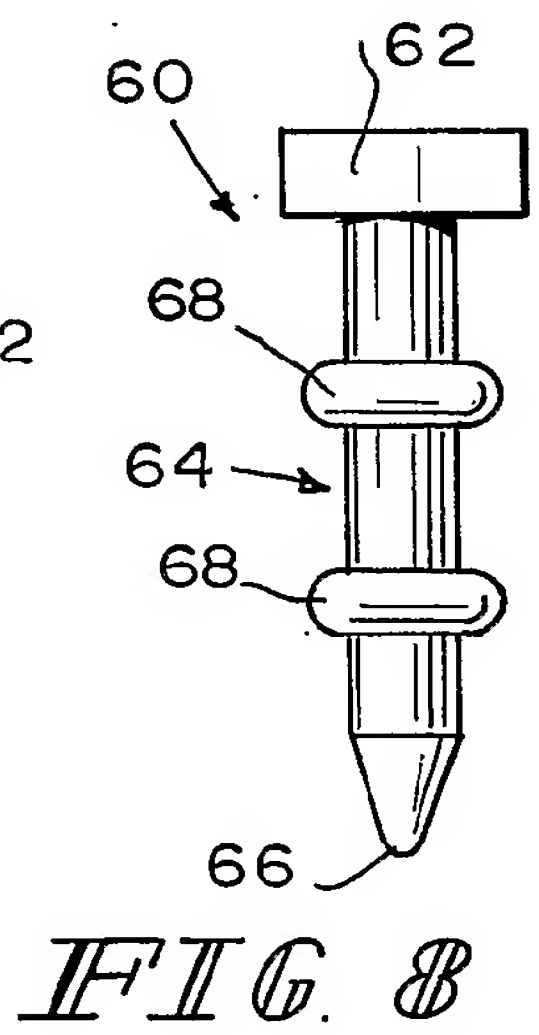
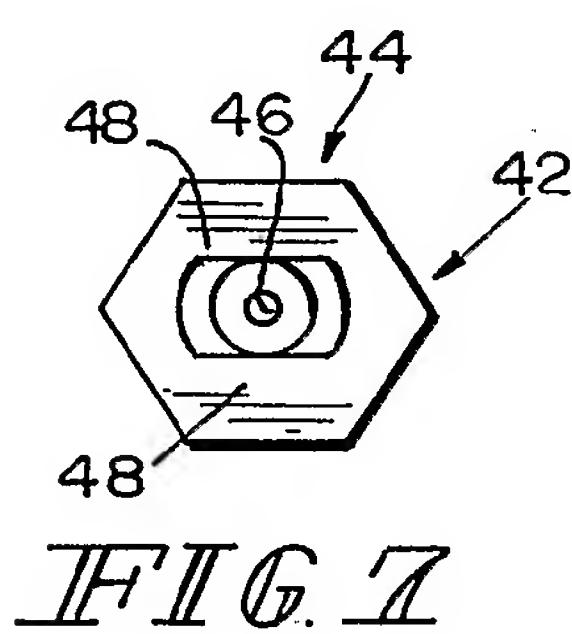
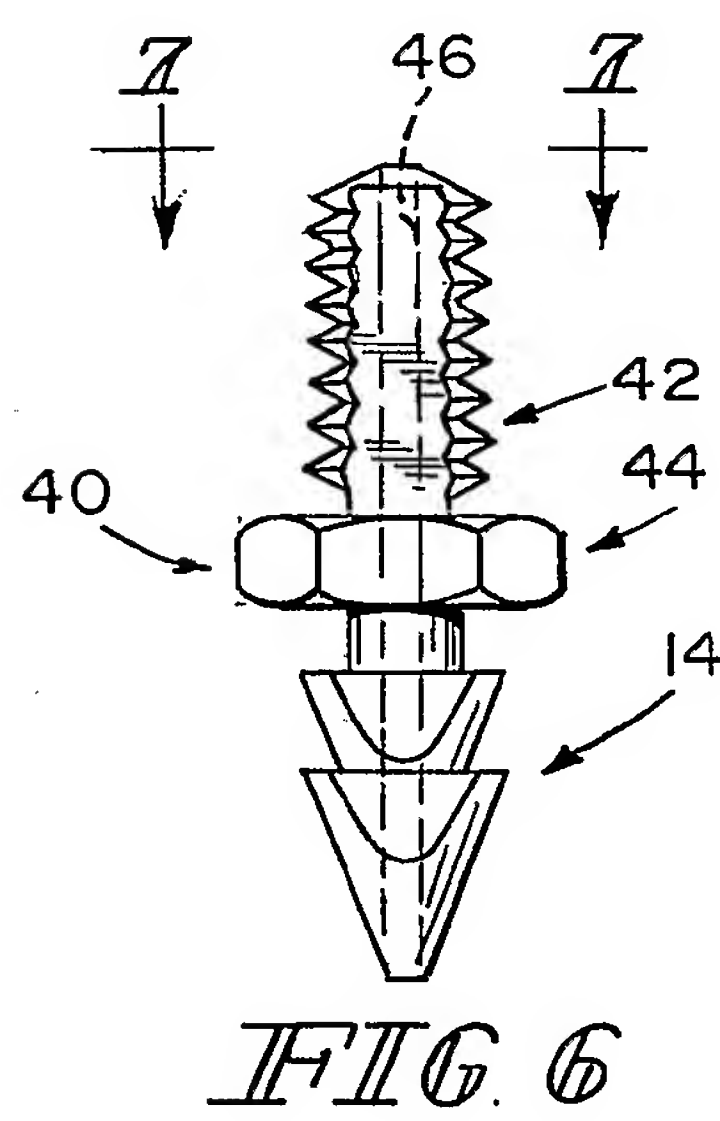
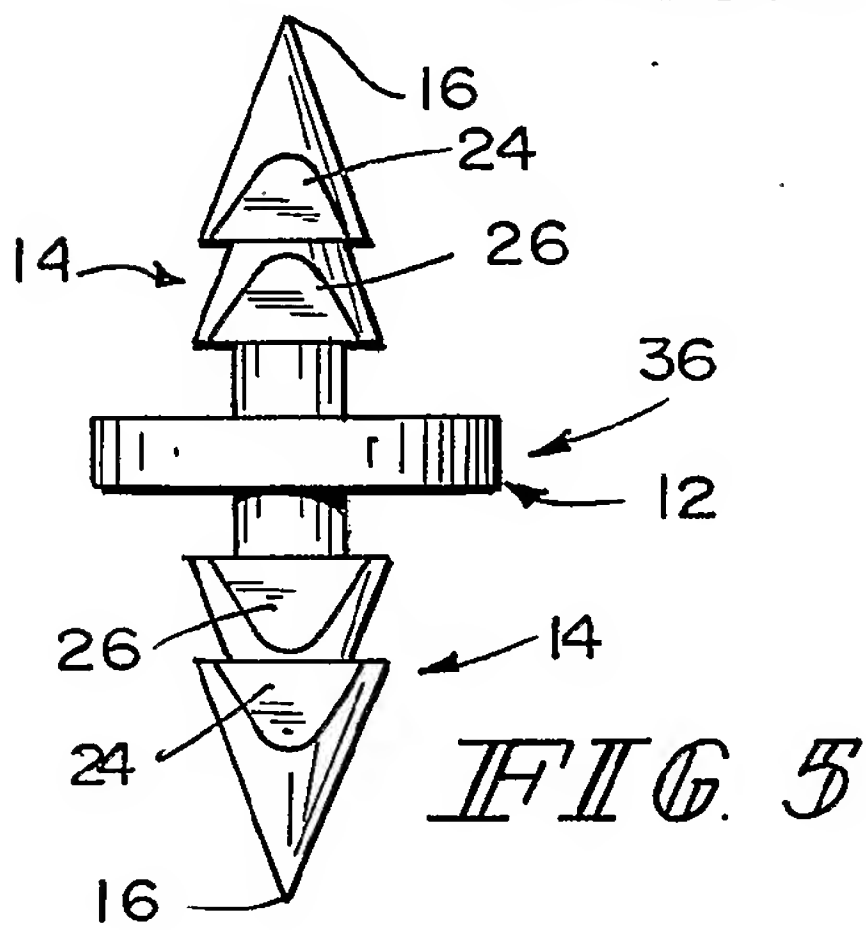
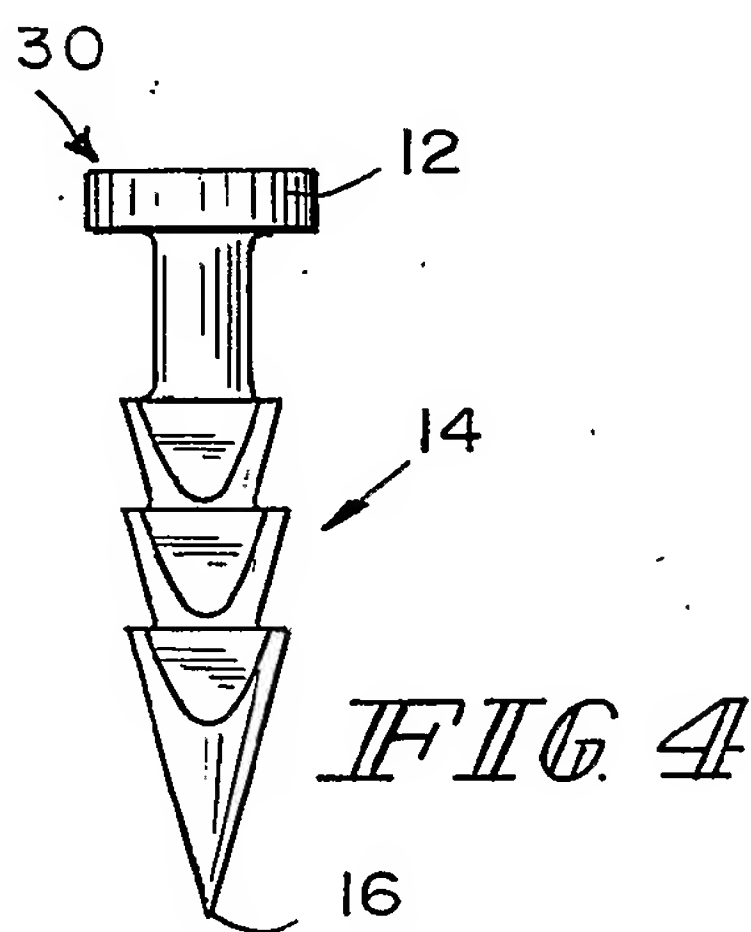
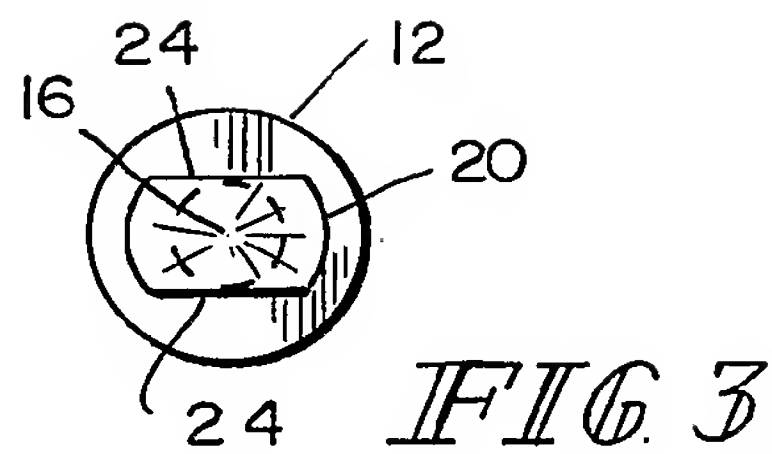
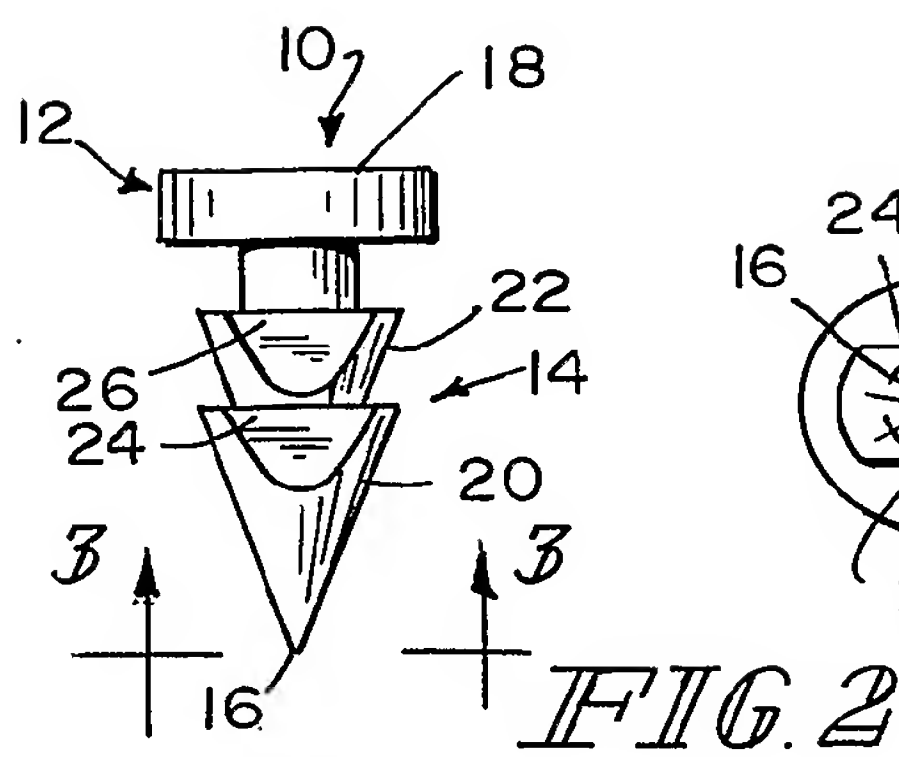
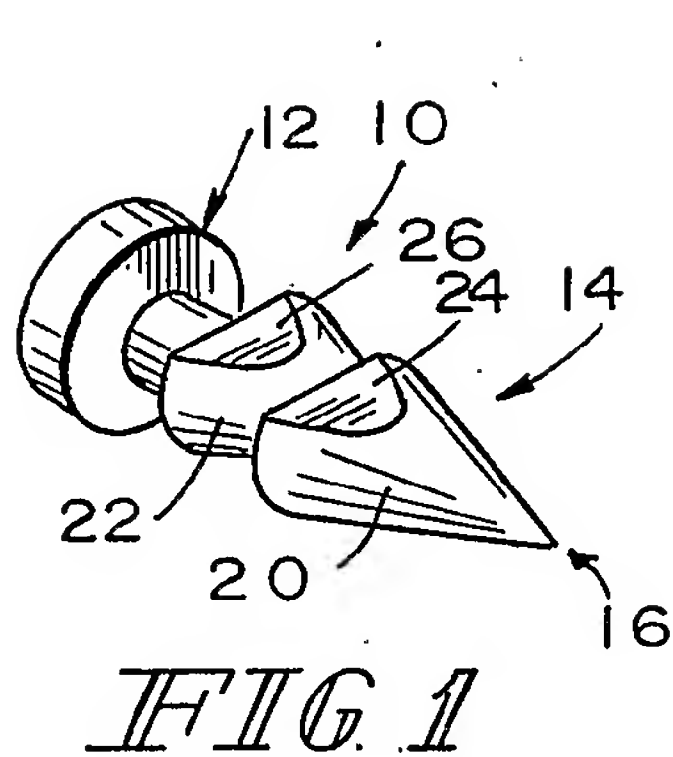
20 an anchor for anchoring a bone plug in an opening formed in bone, at
least part of the device being configured to be wedged between the bone plug and the
bone;

an anchor comprising a body having a channel therein, the body being
configured to collapse inwardly under compression;

25 a meniscal repair device comprising a pair of barbs and a sheet of
naturally occurring extracellular matrix material extending between the barbs;

an outer shell portion and an inner portion surrounded by the shell,
wherein the outer shell portion has a density greater than the inner portion; and

30 a wedge-shaped body having an upper panel and a lower panel
angularly separated to define an apex portion and a base portion, the panels being
formed of a naturally occurring bioremodelable collagenous tissue matrix.



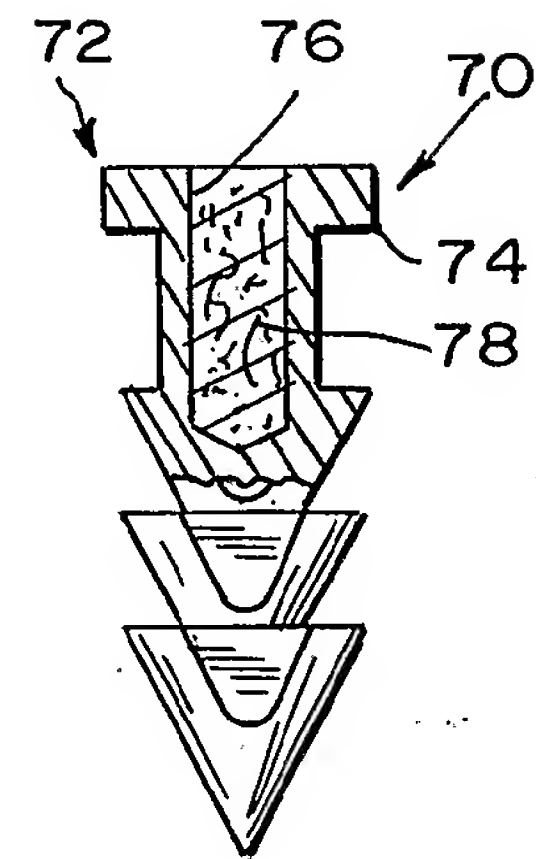


FIG. 10

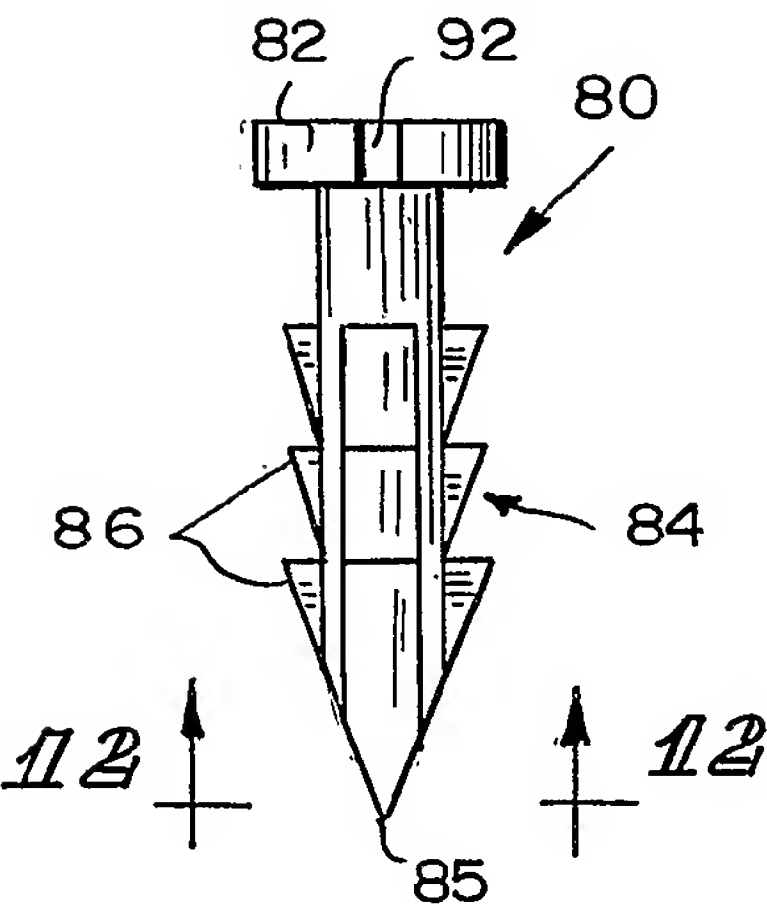


FIG. 11

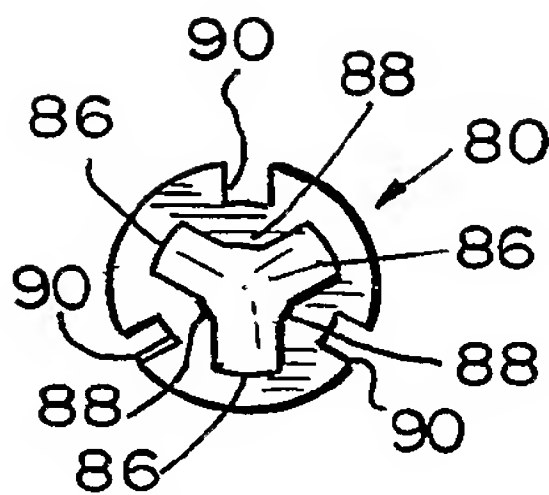


FIG. 12

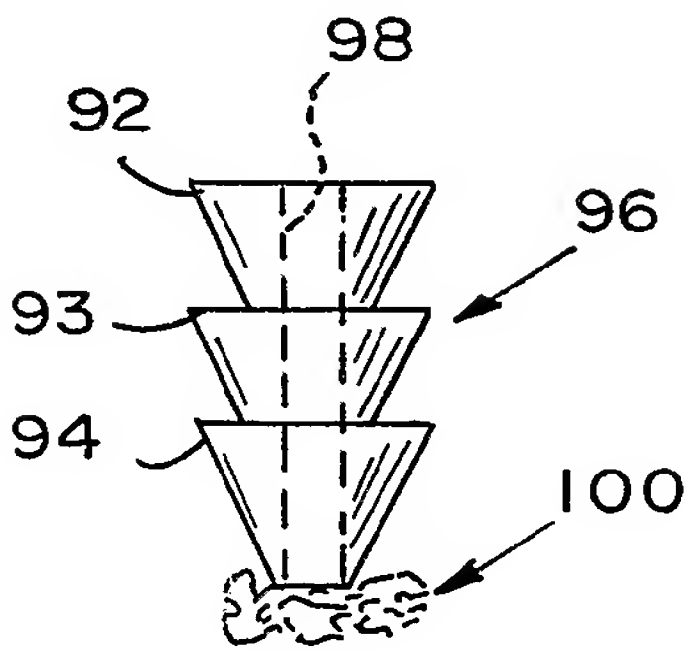


FIG. 9

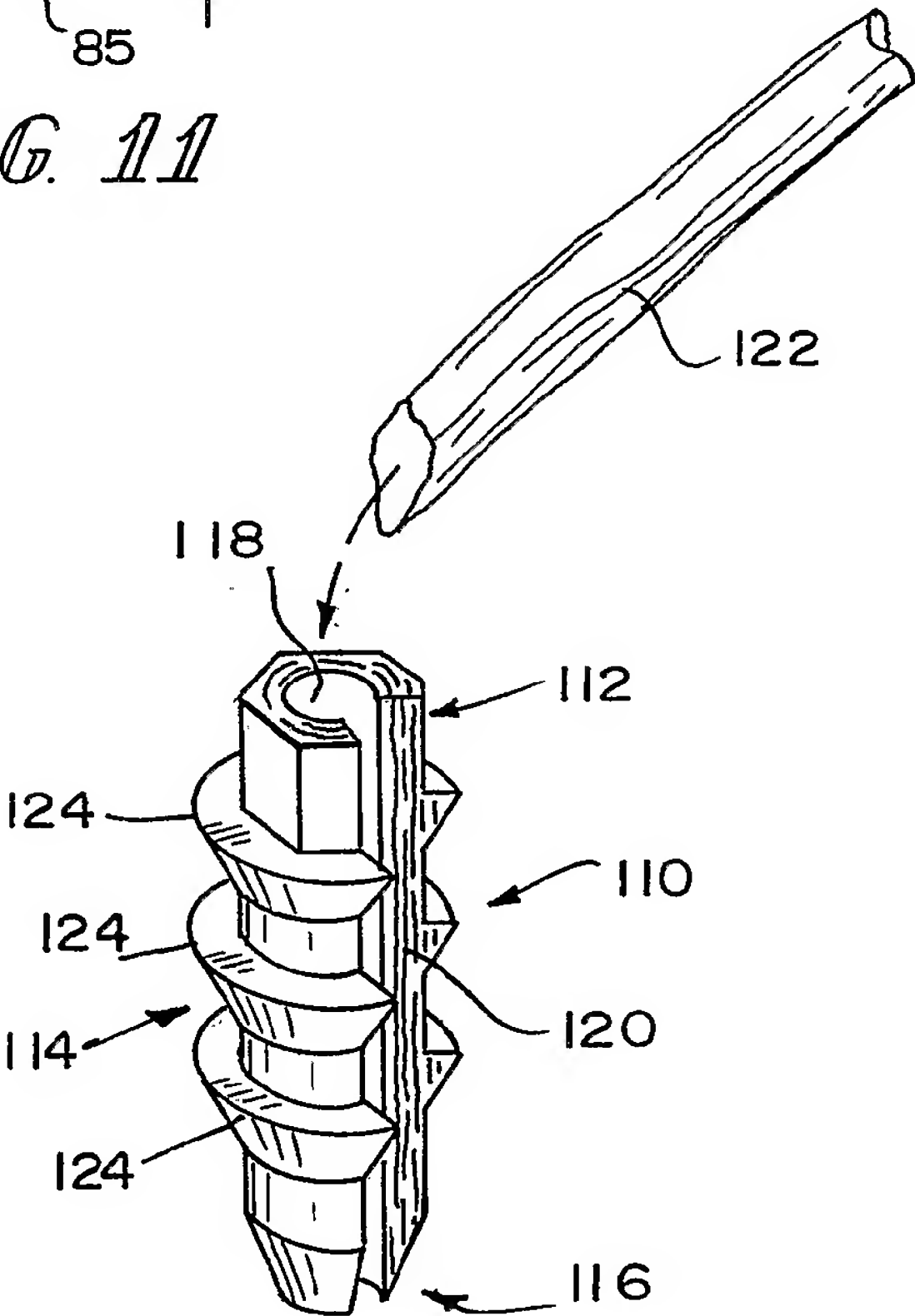


FIG. 13

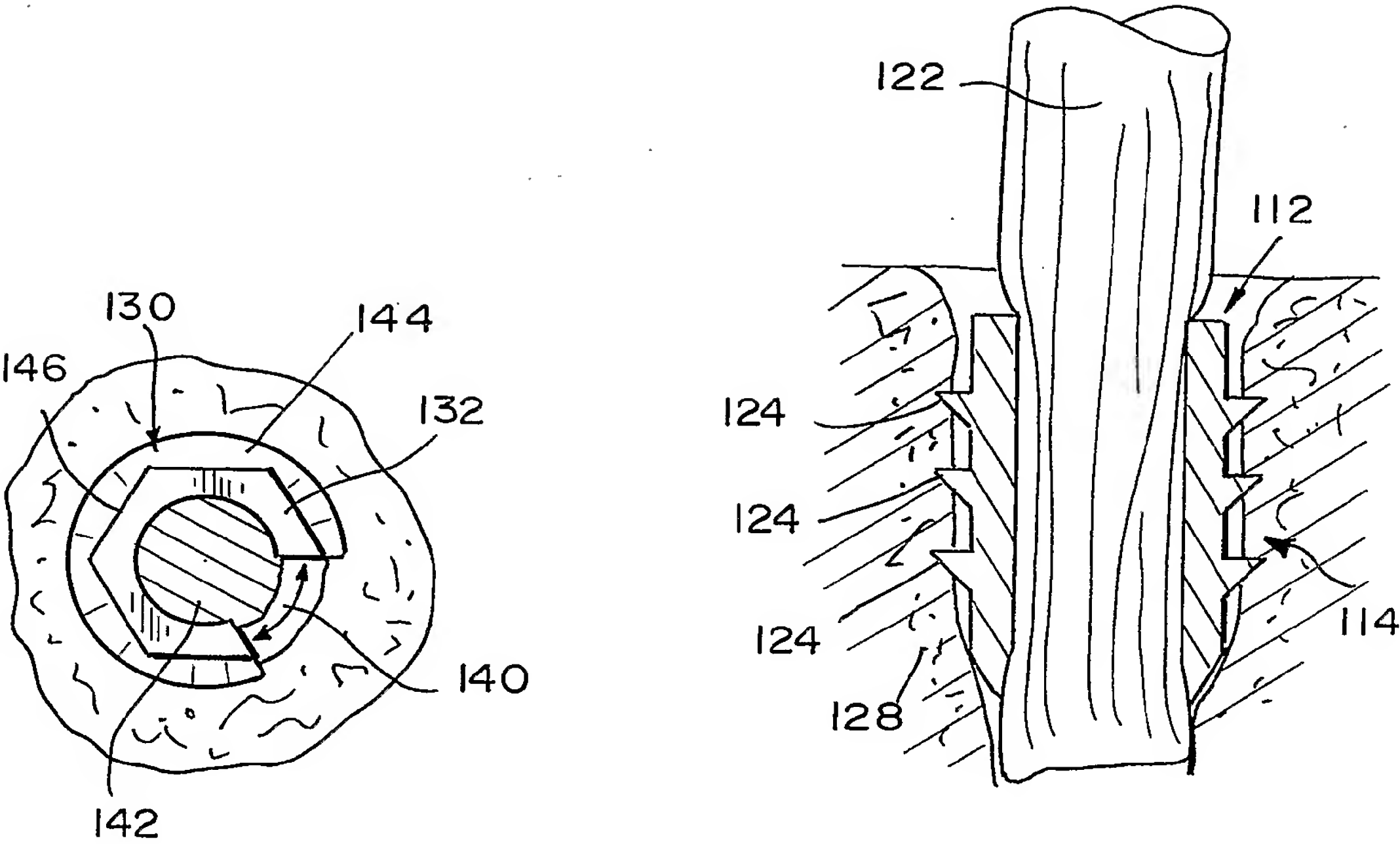


FIG. 15

FIG. 14

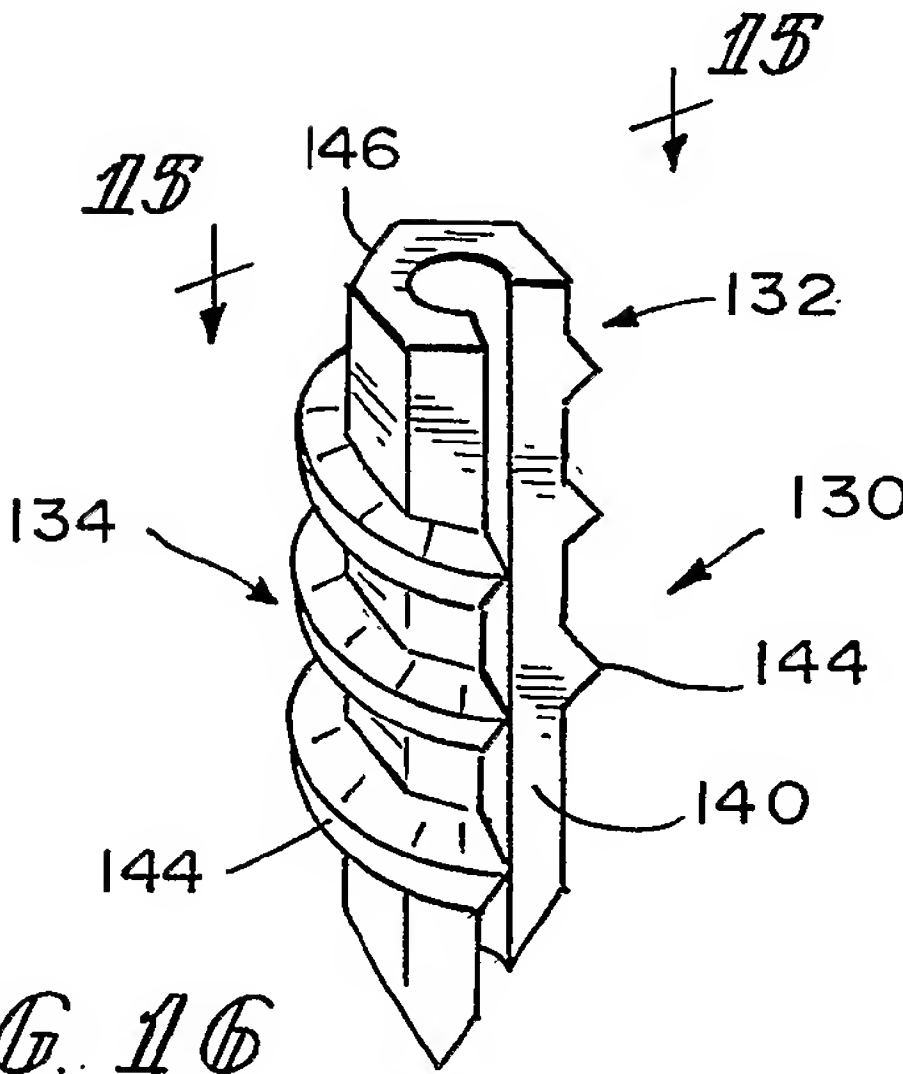


FIG. 16

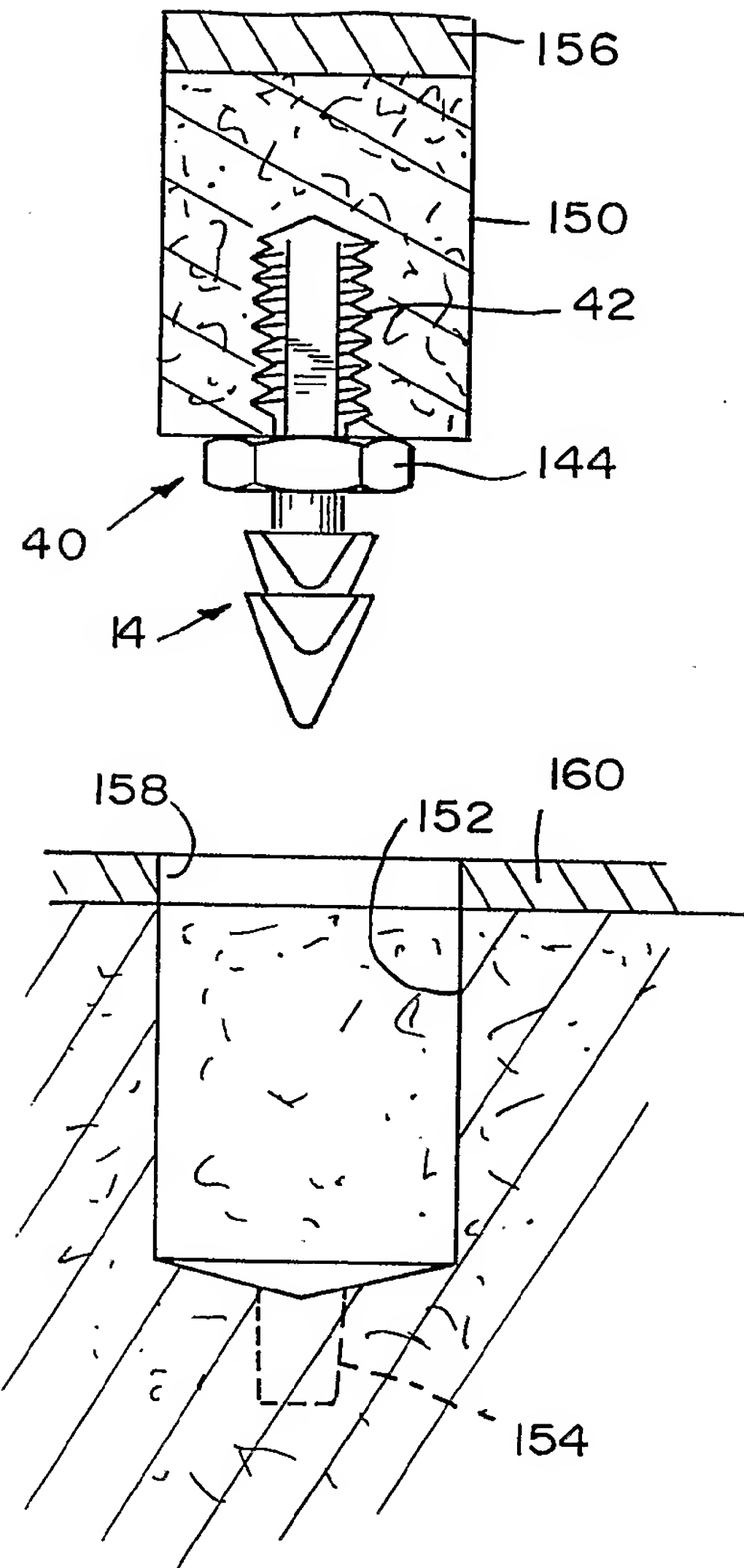


FIG. 17

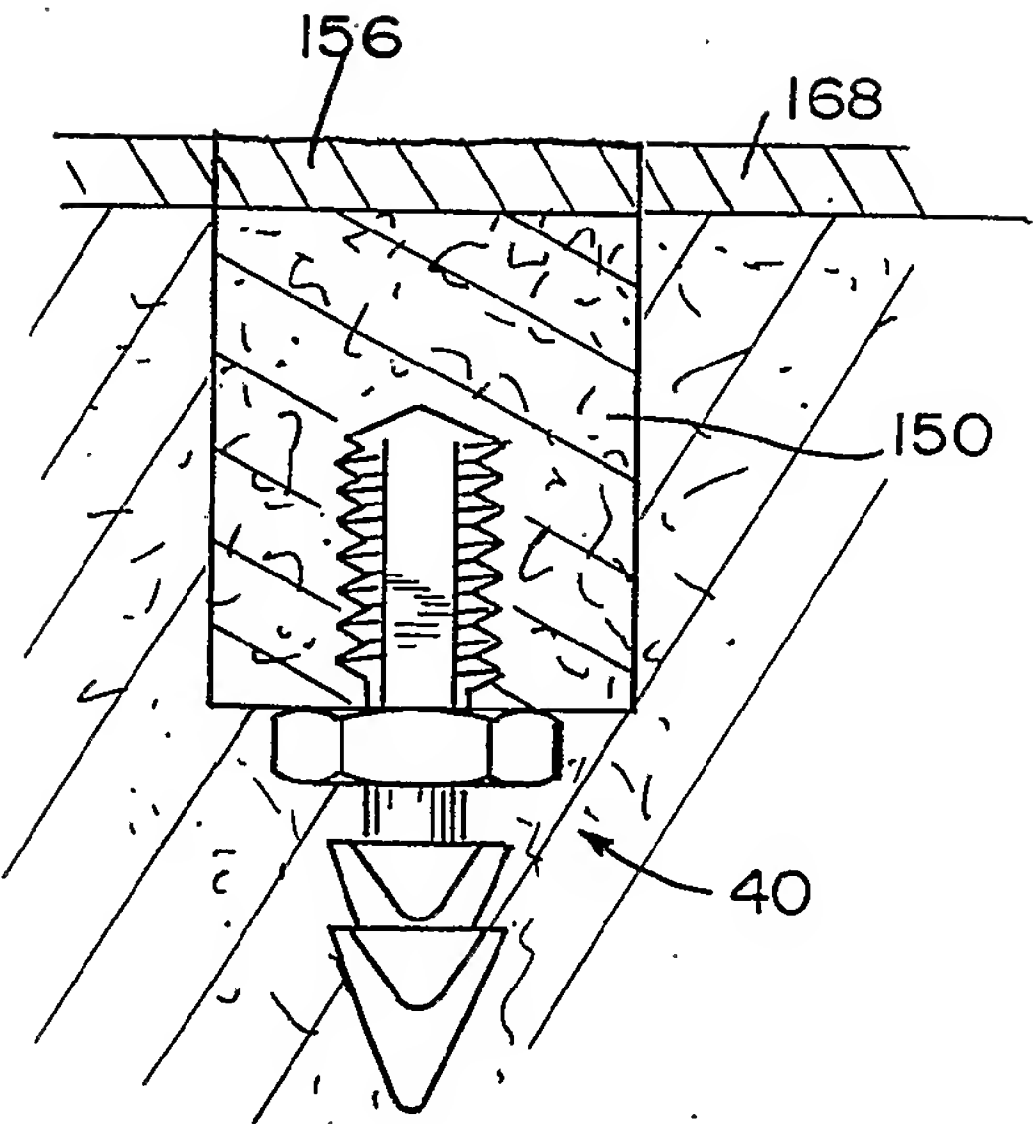


FIG. 18

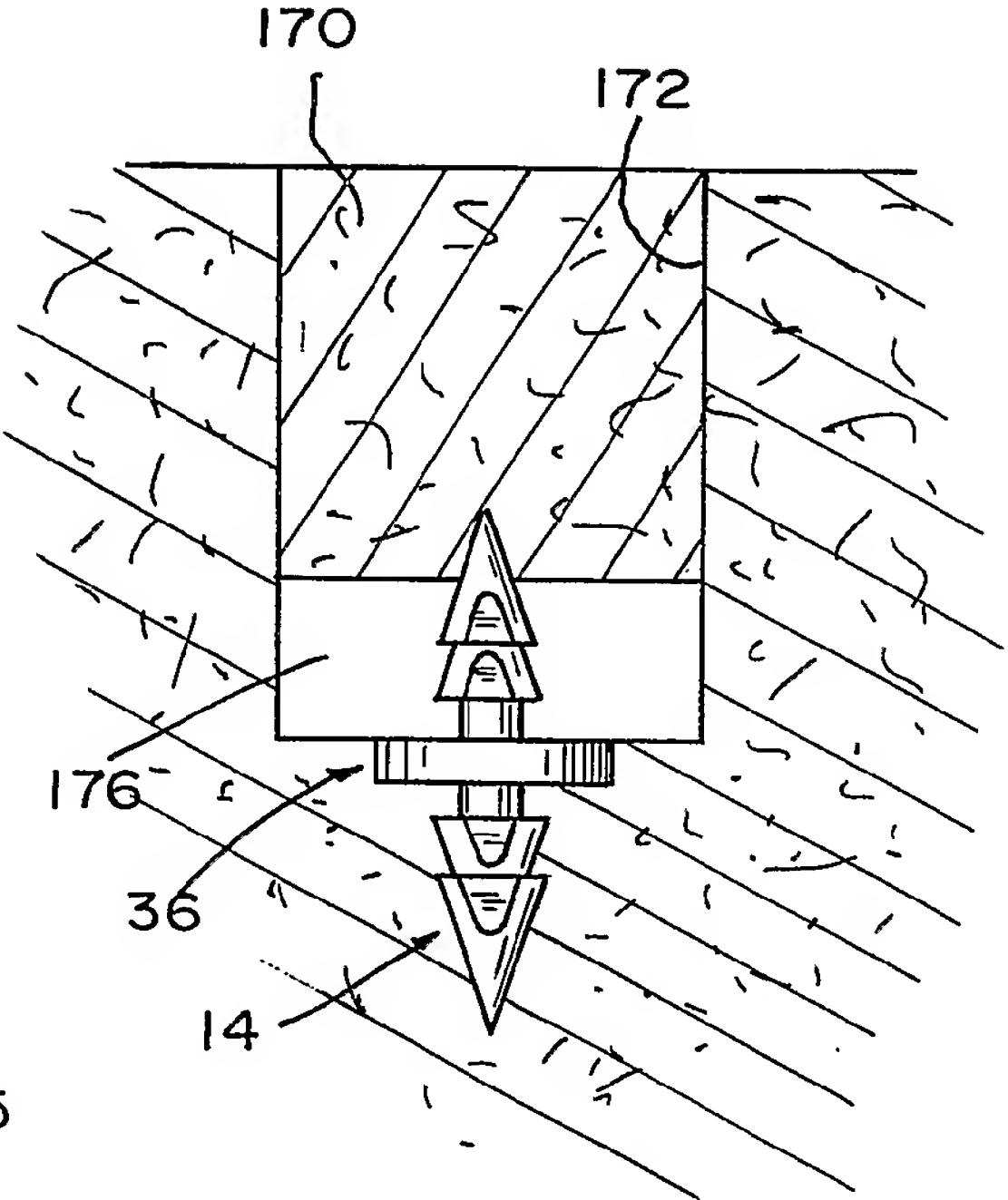
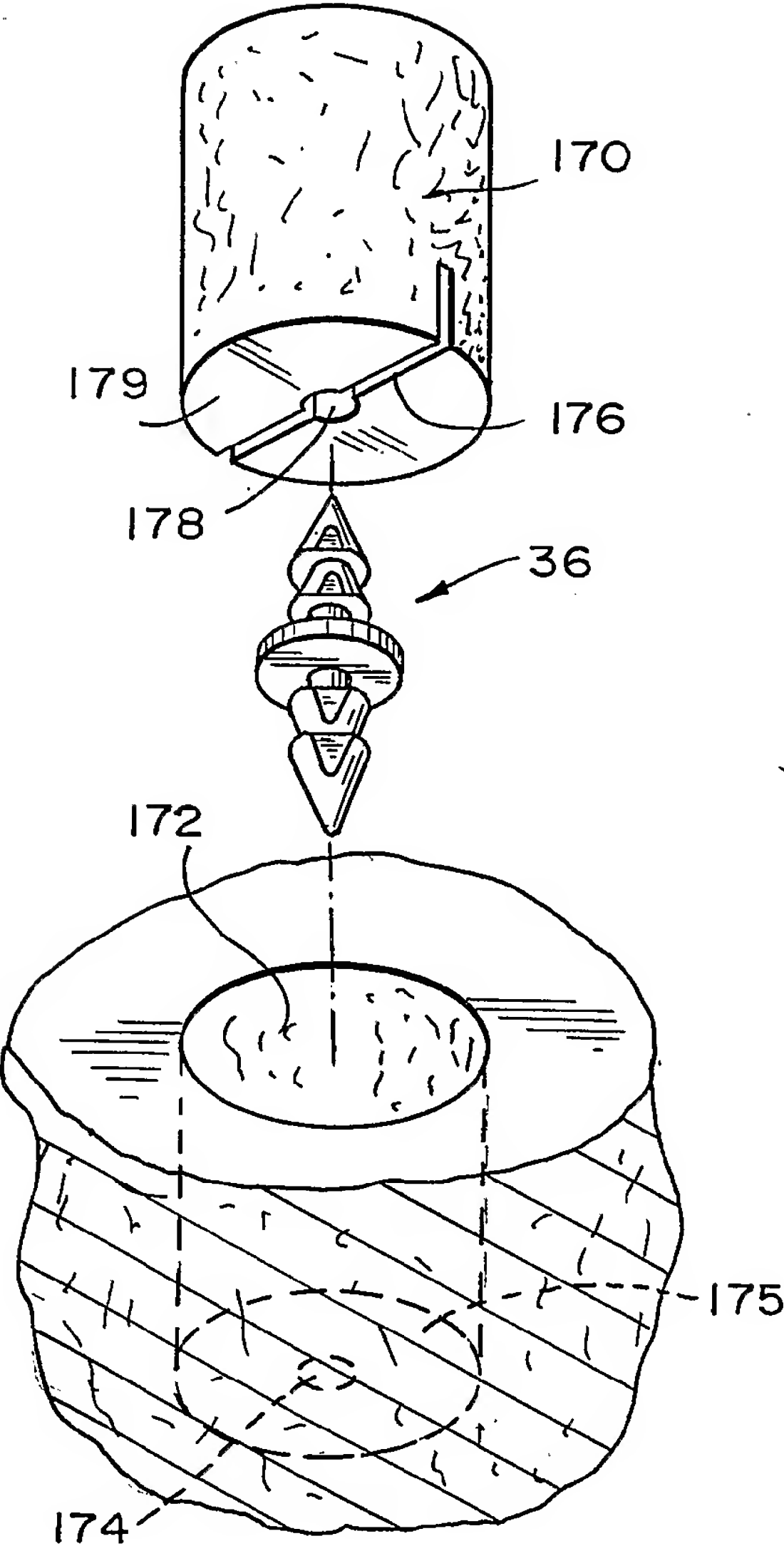


FIG 23

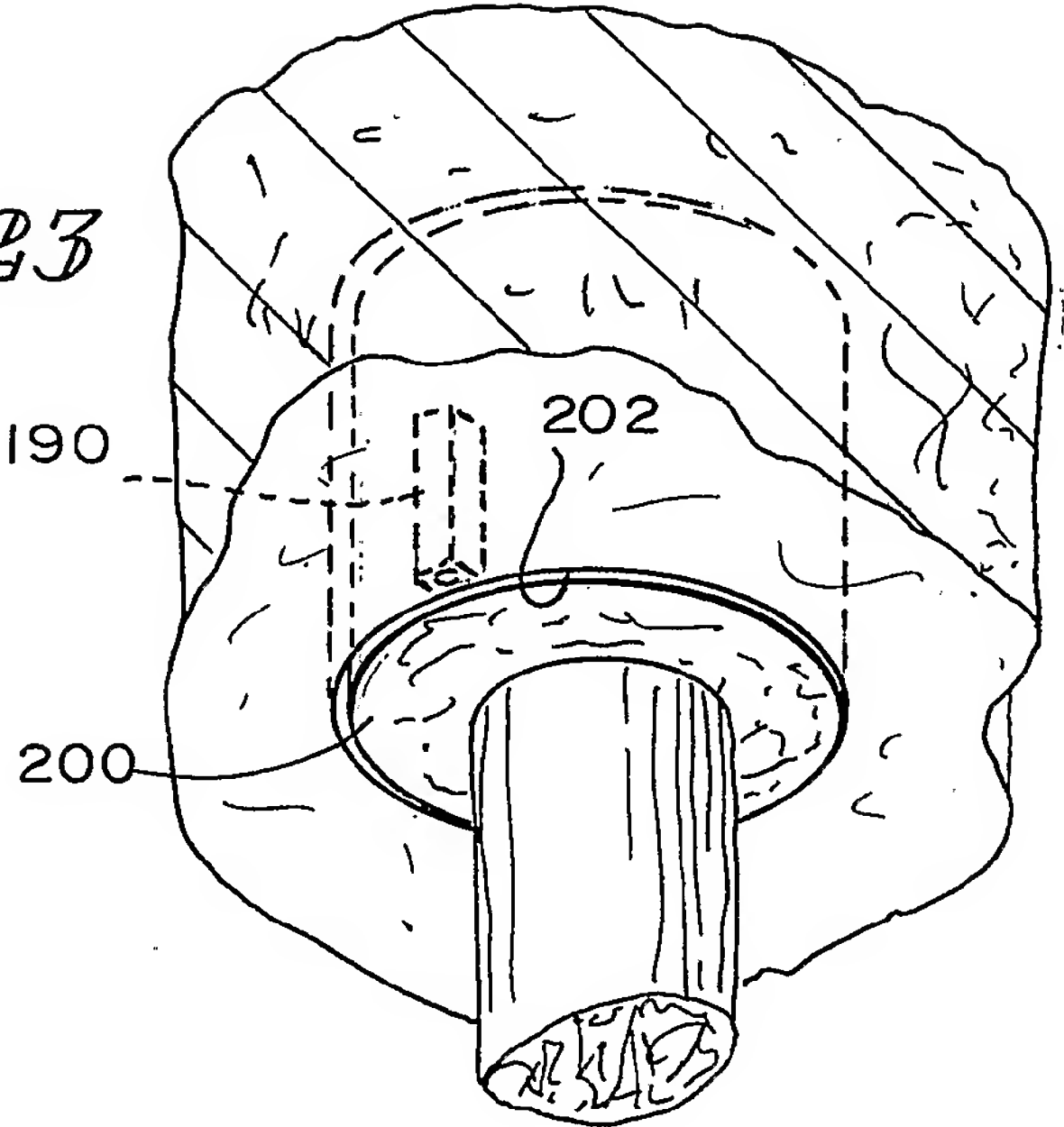


FIG 21

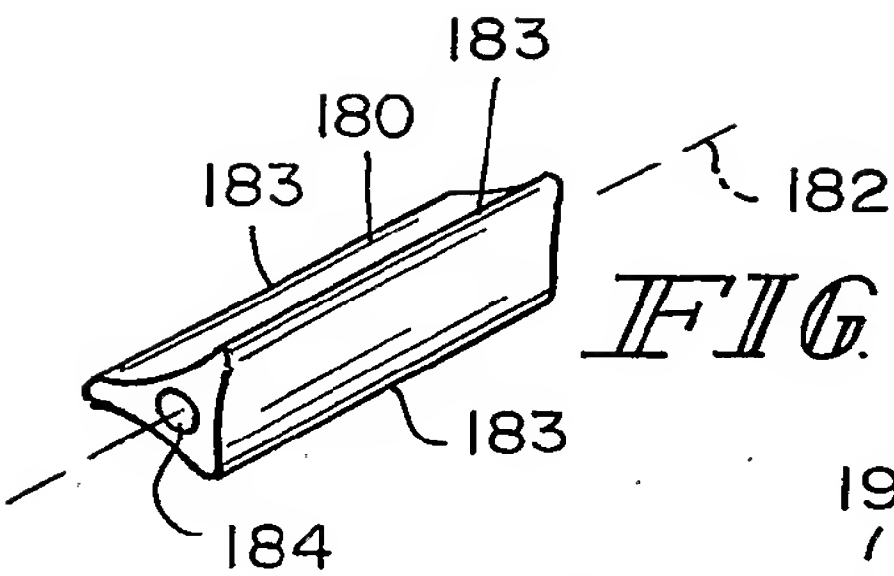


FIG. 22

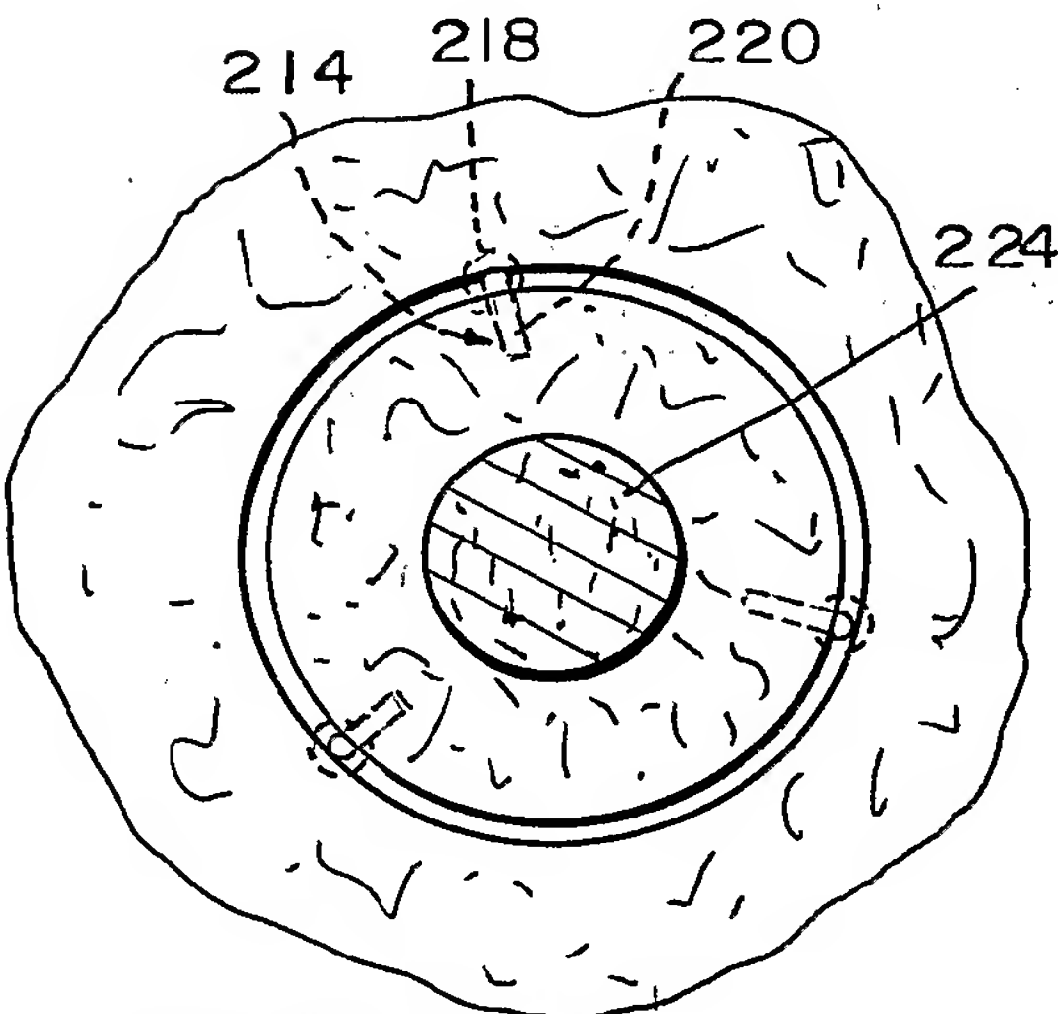
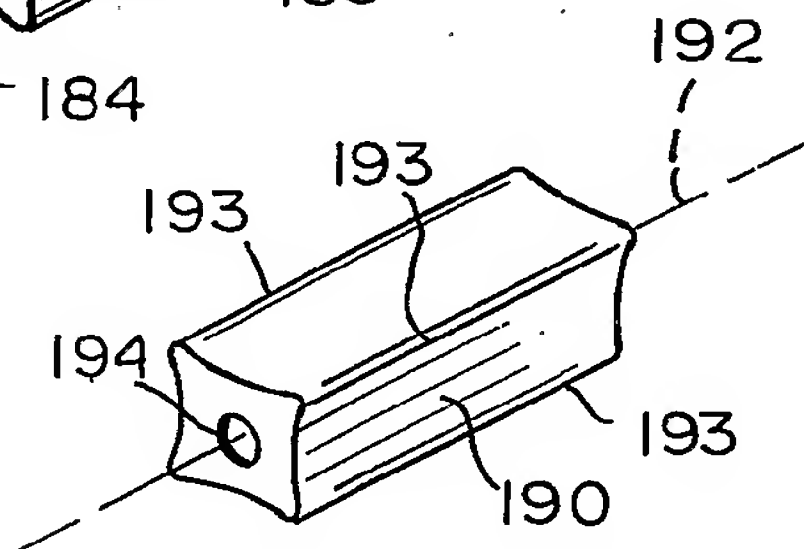


FIG 25

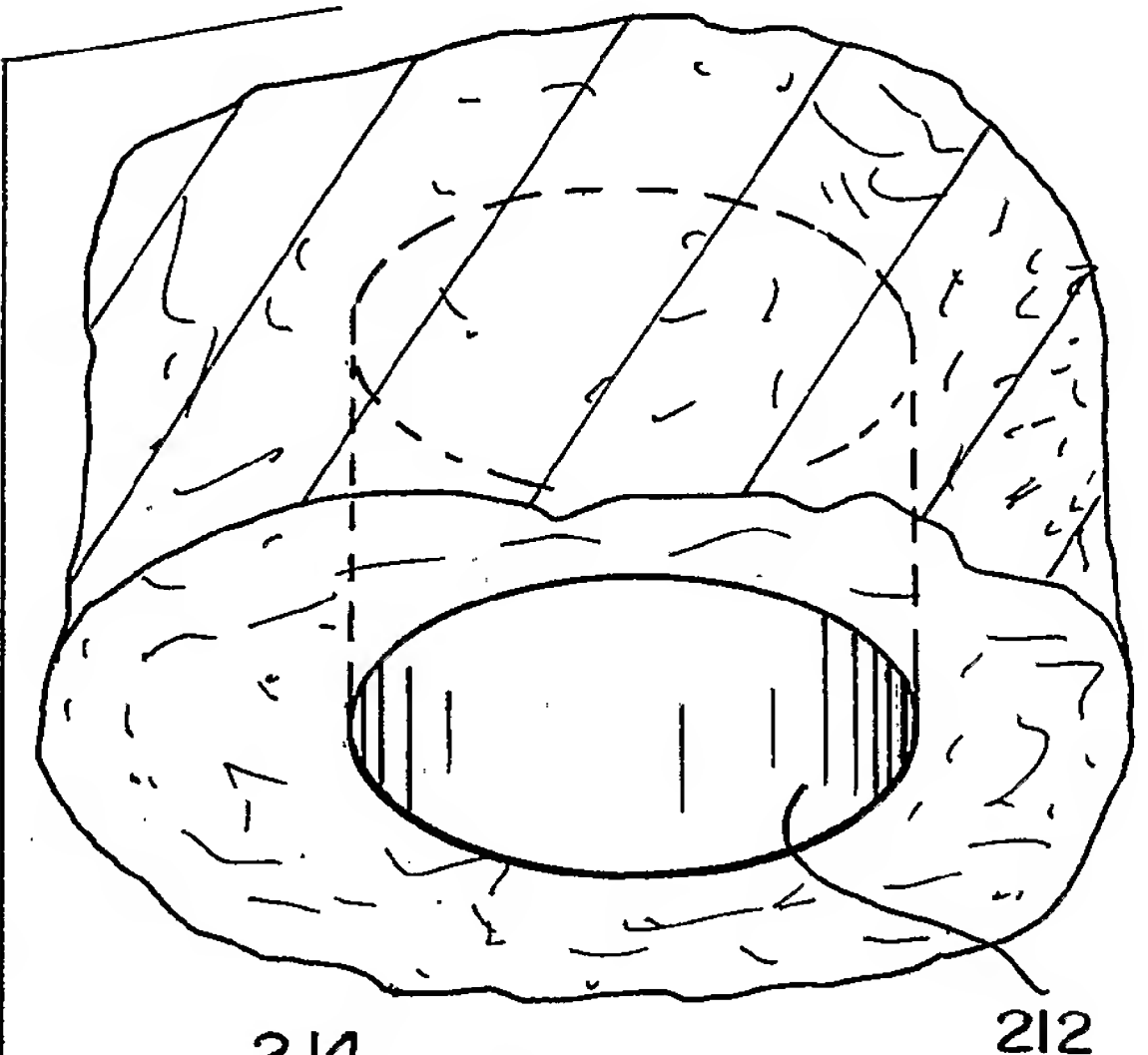
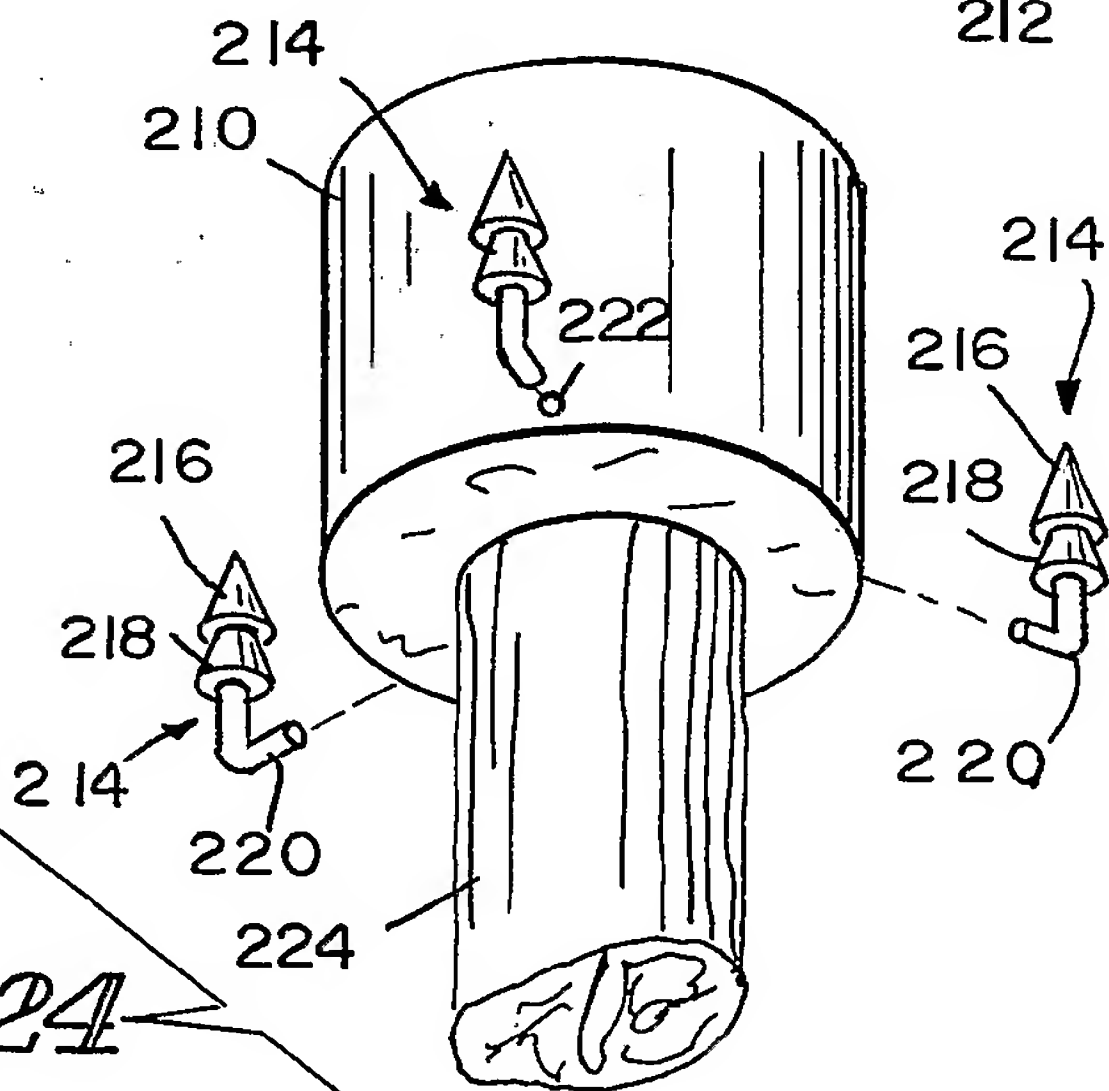


FIG. 24



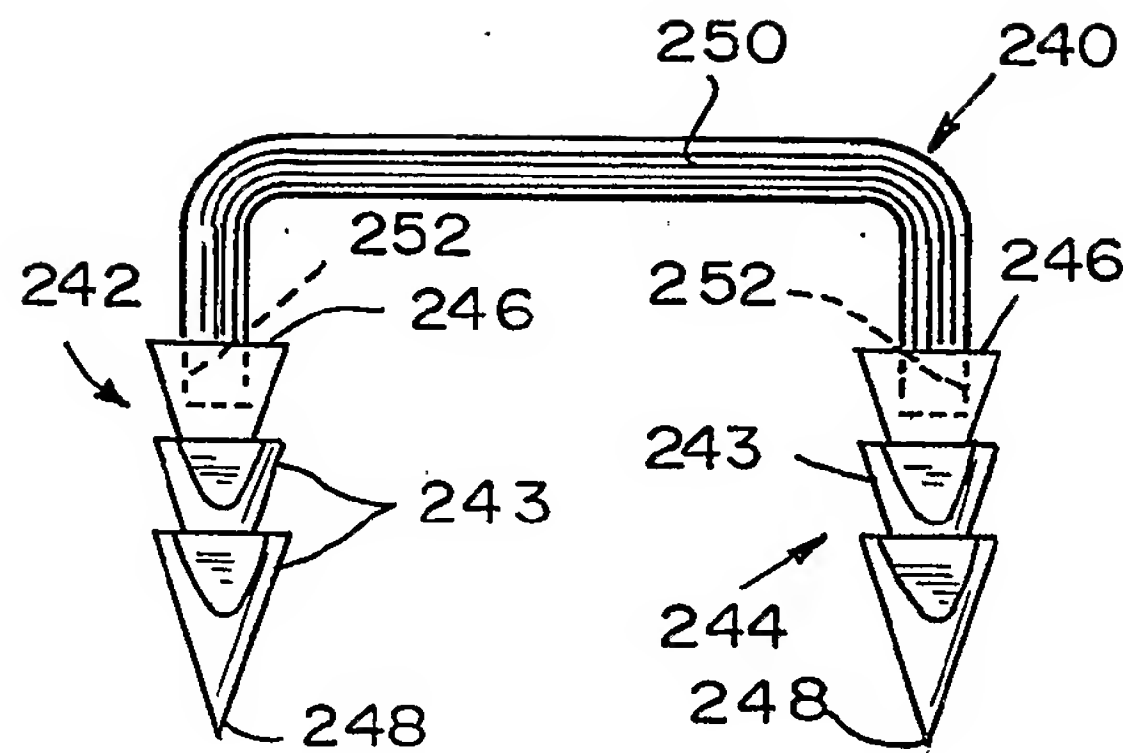


FIG. 26

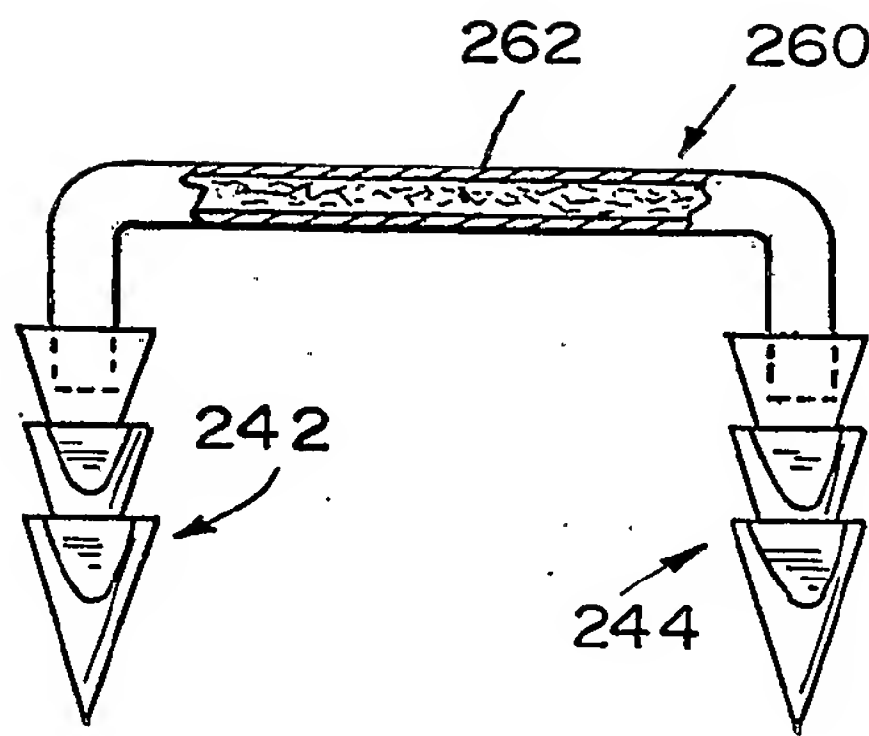


FIG. 27

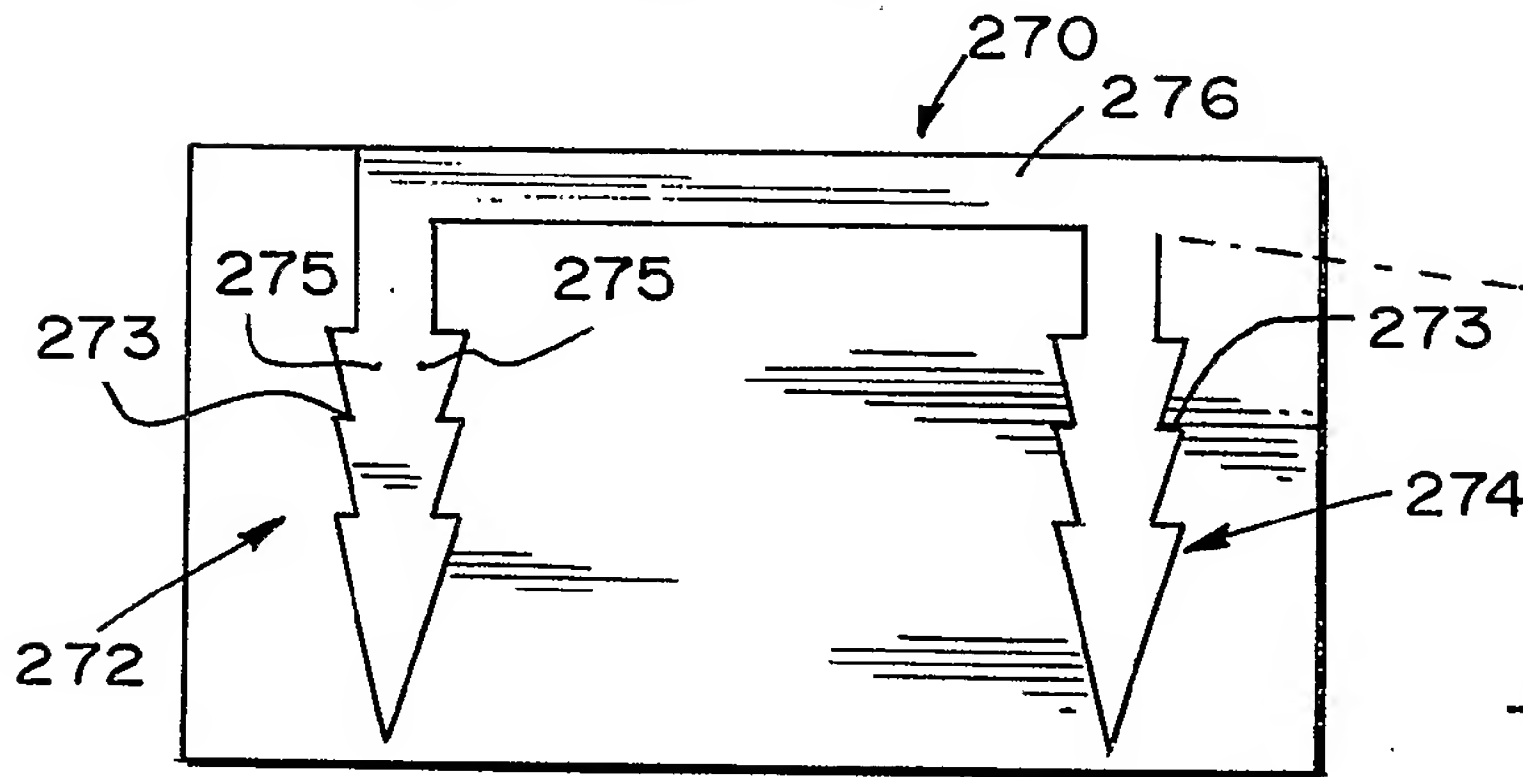


FIG. 28

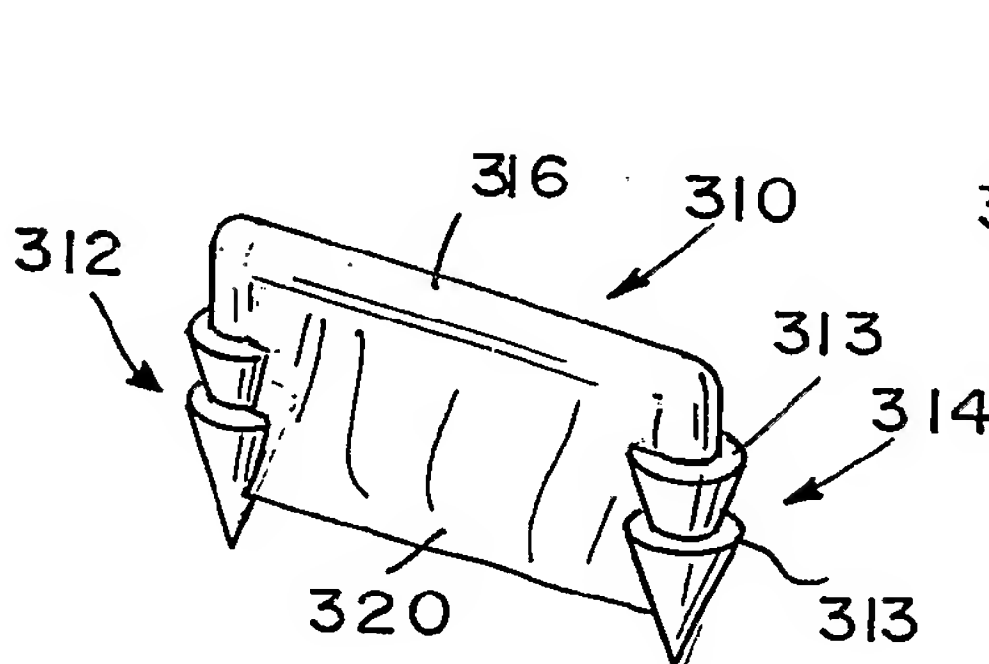


FIG. 29

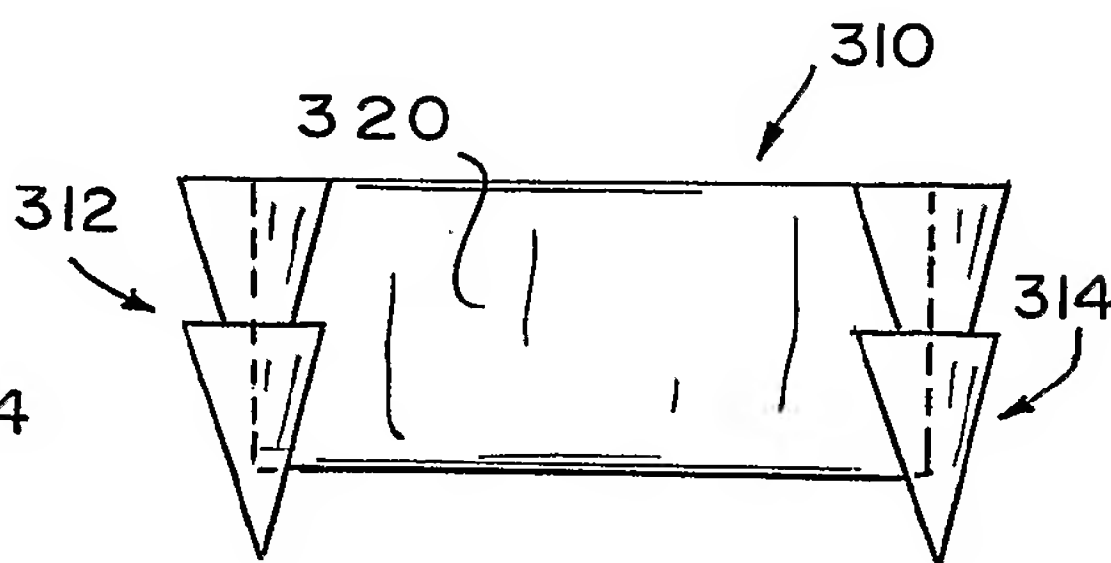


FIG. 29 (a)

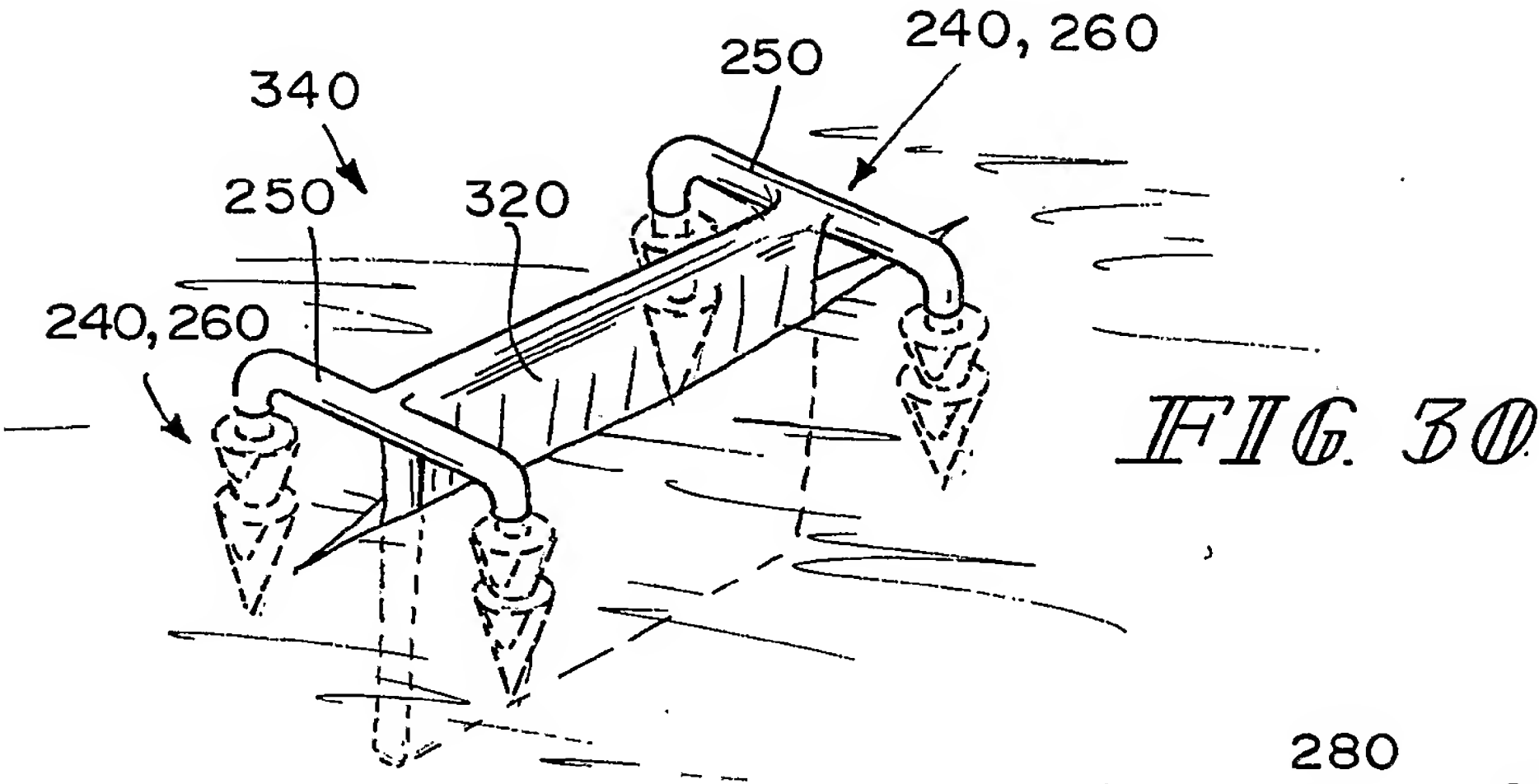


FIG. 31

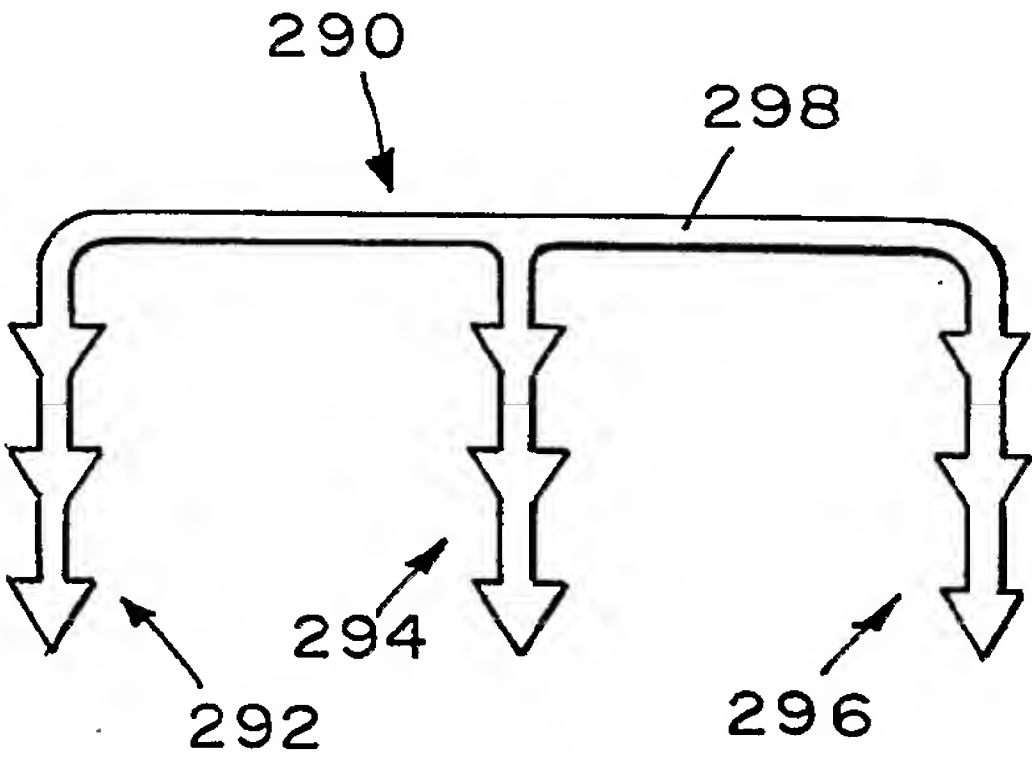
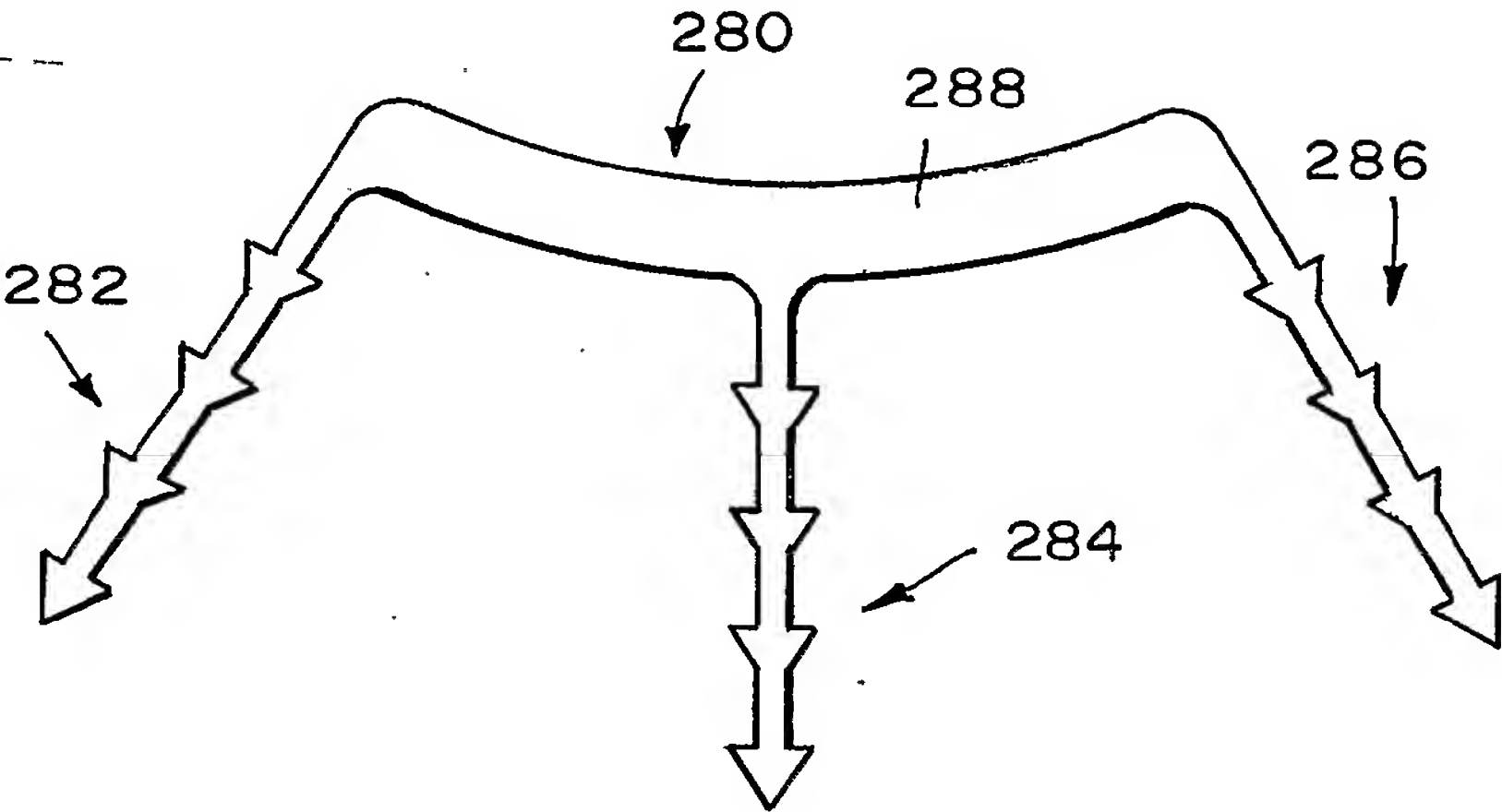


FIG. 32